ASSESSING AND TREATING CHRONIC PAIN IN COMMUNITY-DWELLING OLDER ADULTS WITH DEMENTIA: A SINGLE-SUBJECT APPROACH

By

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Chair: Ann Horgas
Major Department: Nursing

Previous research on pain assessment in persons with dementia has mostly focused on nursing home or hospitalized populations, finding that this subgroup of older adults experiences comparable pain to cognitively intact elders. These studies advocate an analgesic trial to treat pain in this population as untreated chronic pain can lead to excess disabilities, such as depression and functional decline. Currently there are pain treatment guidelines specifically for older adults with dementia. Acetaminophen is the first line drug recommended in pain treatment guidelines for older adults. This feasibility study investigated the effects of acetaminophen in reducing pain behaviors and excess disabilities in community-dwelling persons with dementia. Three participants with severe dementia and their primary caregiver completed 24 daily sessions that allowed the researcher to observe for changes in pain behavior over time following an ABAB study design. During baseline phases (A), pain and excess disabilities were assessed through the completion of daily measurement tools by trained observers and informal caregivers

and videotaped behavioral observations of the participant performing an activity protocol (walking, standing, sitting, and lying) designed to elicit pain. Treatment phases (B) consisted of the administration of the treatment drug, Tylenol Arthritis, 1.3 grams every 8 hours while awake in addition to Phase A procedures. Results show that acetaminophen effectively reduced chronic pain behaviors in this sample of older adults with dementia. The frequency of excess disabilities also showed a general decline throughout the study period. Finally, primary caregivers proved to be moderately reliable proxy informants of participants' pain.

CHAPTER 1
INTRODUCTION

Older adults in today's society are living longer than they did in previous generations. As a result, there is an increased need for understanding the specific healthcare issues that face this segment of the population. One of the most important, yet often overlooked, healthcare issues that needs to be addressed is that of proper assessment and management of chronic pain. Chronic pain, sometimes referred to as persistent pain, is defined as pain lasting longer than 3 consecutive months in duration. Pain is a complex phenomenon that affects each individual differently. In order to understand the exact nature of an individual's pain experience, it is necessary to elicit his or her own interpretation of this experience. Pain has been described in a variety of ways, such as "an individual's perception of a sensation which is noxious and uncomfortable, and one from which escape or relief is sought" (Weissman & Matson, 1999, p. 31) or as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described of in terms of such damage" (Price, 1988, p. 6). Perhaps the most common definition of pain, suggested by McCaffery and Beebe (1989), has been that pain is "whatever the patient says it is and occurs whenever the patient says it does" (p. 7).

Clearly, each definition recognizes the role of the individual in interpreting the experience of pain. Most individuals who experience pain can recognize its onset and can outwardly express this pain, usually through verbal reports. After interpreting their pain, they can seek pain relief through a variety of pharmacologic and/or

nonpharmacologic forms. Effective pain management can exert a positive influence in many aspects of an individual's life as pain has been shown to be related to depression and weight loss, and to interfere with activities of daily living, sleep routines, social behavior, functional status, and quality of life (Ferrell, 1995;Villanueva, Smith, Erickson, Lee, & Singer, 2003; Warden, Hurley, Volicer, 2003). However, there are groups of people, such as those with dementia, in whom verbal reports of pain are either unobtainable or unreliable. How does this normal encoding and decoding of the pain experience apply to persons with dementia who, due to the nature of the disease, have barriers in the ability to express themselves? This question serves as the foundation for this study.

Background and Significance of the Problem

It has only been within the last 15 or so years that researchers have begun to study the assessment of pain in persons with dementia in order to find a way to detect meaningful behaviors indicative of pain (Hurley, Volicer, Hanrahan, Houde, & Volicer, 1992; Villanueva et al., 2003; Warden et al., 2003;). These studies have shown promising results. Recognizing that the presence of dementia complicates pain assessment in these persons due to both the cognitive and verbal deficits that accompany this disease, these researchers have concentrated on identifying observable behaviors such as facial expressions, body movements and postures, as well as vocalizations that are considered to be indicative of pain.

The recent progress that has been made in this area has evolved from research studying pain in general. It should be noted that the study of pain has a relatively short history itself, gaining popularity only within the last several decades. First, researchers focused on finding reliable ways to assess pain in the normal adult population. The most

commonly used method of pain assessment in this population is through self-report. Simple rating scales allow a person to quantify the intensity of his or her internal painful experience in a measurable way. From these research endeavors, tools such as the Numeric Rating Scale (NRS), the Verbal Descriptor Scale (VDS), and the Visual Analog Scale (VAS) have been developed to measure pain. Each of these tools consists of a scale anchored at 0 (meaning no pain) with increasing numbers that represent increasing amounts of pain, and in the case of the VDS, verbal descriptors that represent incrementally higher levels of pain. Tools like these also allow for measuring the effectiveness of pain treatment by comparing pre-treatment pain intensity ratings to post-treatment pain intensity ratings.

As is natural in the course of research, once reliable measures of pain were found in the normal adult population, researchers could begin to expand the study of pain assessment into other populations and to specific causes of pain. Studies have shown that both the VDS and NRS are reliable and easy to use with an elderly population (Gagliese & Melzack, 2003; Herr & Mobily, 1993). Once pain research was expanded to include older adults, researchers found a common theme in most study results in that the 65+ age group had the highest self-reported pain prevalence rates (Gibson & Helme, 1995). Yet, pain in this population is often dismissed as a normal consequence of aging. Recent studies, however, have indicated that this is not the case (Edwards, Fillingim, & Ness, 2003; Gagliese & Melzack; Harkins, 1996; Helme & Katz, 2003). There is evidence that some underlying pathology is involved, with osteoarthritis (OA) of articular joints being one of the most common causes of chronic pain in older adults. In fact, the presence of OA in adults over age 65 is twice that of younger adults (Gibson & Helme). Clearly,

research efforts in this area have shown that older adults do experience pain and report higher pain prevalence rates than do younger adults.

Building on these findings, researchers have had the basis to propose that pain may affect all older adults experiencing a disease process that typically has pain as a symptom. Even though research studies have found the highest pain prevalence rates in those 65 and older, most investigators believe that older adults underreport the intensity of their pain. This belief has been validated recently by Labus, Keefe, and Jensen (2003) in a review of 30 studies that compared the correlation between self-reported pain intensity and direct observation of pain behaviors, which resulted in only a moderately positive relationship ($r = 0.26$) on average, across the studies. Several theories have been proposed as to why older adults underreport their painful symptoms. In cognitively intact older adults this could be due to their diminishment of the importance of mild pain, attributing it to the normal aging process (Gagliese & Melzack, 2003; Gibson & Helme, 1995) or because of their fear about what an intensification of painful symptoms might mean (i.e. worsening of a disease process, need for diagnostic testing, or impending death) (Herr, 2002). These theories led the Joint Commission on Accreditation of Health care Organizations (JCAHO) (2001) to recognize pain assessment as the 5th vital sign, requiring healthcare professionals to systematically ask about its presence rather than to rely on the hospitalized patient to volunteer information. There is one fatal flaw in using only self-report to measure pain (whether volunteered by the individual or elicited by another party): this method is not applicable to all populations. For instance, infants can no better report their pain level than can older adults with the compromised cognitive and verbal abilities of dementia.

For these reasons, researchers have recently focused efforts on ways to reliably assess pain in persons with dementia. The most valid and reliable way found has been to look for observable behavioral indicators of pain. Keefe (1982) modeled this approach for other investigators when he found that he could reliably assess pain by observing pain behaviors in people with chronic low back pain, looking specifically for guarded movements, bracing, rubbing, grimacing, and sighing. Although the participants in his study were not cognitively impaired, his work in this area allowed researchers to take these behaviors indicative of pain and to observe for them in persons with dementia. In fact, Hadjistavropoulos and Craig (2002) reported findings from studies showing similar behavioral displays of pain observed for both cognitively intact and impaired participants. As mentioned previously, several researchers (Hurley et al., 1992; Villanueva et al., 2003; Warden et al., 2003) have found valid and reliable behaviors that indicate the presence of pain in persons with dementia.

While the majority of these research studies have looked at behaviors in persons with dementia residing in nursing homes, it is important to study these behaviors in a community-dwelling sample as well. This is especially true because of the estimated 4.5 million persons with Alzheimer's disease, more than 70% live at home where nearly 75% of their care is provided by family and friends (Alzheimer's Association, 2006). Now that pain behaviors have been identified in persons with dementia, research efforts need to shift gears so as to focus on ways to treat this pain. While guidelines exist for pain treatment in older adults in general, there are no specific guidelines for treating pain in persons with dementia, largely because there has been little work done in this area.

Rationale and Need for this Study

Due to the questionable use of self-report for pain assessment in persons with dementia, researchers have developed and employed behavioral observation strategies in this population with success and have determined that people with dementia do experience pain. The next logical step is to try to do something about the pain. This is an area of research, and clinical practice as well, that warrants further development. In general, pharmaceutical studies have excluded persons with dementia from drug trials, thus preventing this group of vulnerable elders from benefiting from research outcomes (Ancill, 1995). It is necessary to identify effective treatments for pain in persons with dementia because of the possible link between untreated or undertreated chronic pain and excess disabilities, such as depression, declines in functional performance, and sleep and behavioral disturbances (Gibson & Helme, 2000; Villanueva et al., 2003). In relation to persons with dementia, the term 'excess disabilities' has been used to describe "reversible symptoms that are undesirable and temporary extensions of a specific primary disability" (Kolcaba, 2003, p. 3). Because most studies assessing pain in older adults with dementia have been focused on institutionalized persons with moderate to severe dementia, this study will also fill a gap by addressing the pain management needs of persons with dementia who remain residing in the community, typically with informal family caregivers.

Several researchers have called for the need of an analgesic trial to treat pain in persons with dementia. Kovach, Weissman, Griffie, Matson, and Muchka (1999) developed the Assessment of Discomfort in Dementia (ADD) protocol which was able to more accurately assess signs of discomfort in persons with dementia, and most importantly, to increase the use of scheduled analgesics to reduce discomfort in these

persons. Their findings also support the belief that the pain experienced by people with dementia is amenable to treatment. The authors note that one limitation of these results is that only the use of scheduled analgesics, not prn or "as needed" analgesics, increased. However, prn analgesics, such as acetaminophen, have incredible potential for treating chronic pain, but are often not given because nurses are trained to give prn analgesics in response to verbal reports of pain.

Acetaminophen (Tylenol) is one of the most commonly used analgesics for the treatment of chronic pain associated with musculoskeletal conditions. Farrell (2002), reports that pharmaceutically, acetaminophen is the most widely used analgesic and antipyretic agent in the United States and the world. As long as dosing instructions are followed, there are few, if any, risks associated with taking acetaminophen. In fact, two of the major benefits of using acetaminophen as an analgesic are its availability over the counter and its relatively low cost. As described below, all of the current treatment guidelines recommend acetaminophen as the first line drug of choice for older adults. The purpose of this study, then, is to evaluate the effectiveness of an acetaminophen trial in reducing the expression of observable pain behaviors and excess disabilities related to chronic pain in community-dwelling persons with dementia, as assessed by trained observers and informal caregivers.

Theoretical Framework

The specific role of theory in the design and conduct of research studies is that of a foundation from which to organize thoughts and hypotheses. Theories then serve as guides for researchers to use to describe, interpret, and prescribe interventions (Meleis, 1997). Research without theory produces isolated information, but research with theory produces science (Alligood & Tomey, 2002). The choice of a guiding theory is a critical

component of the research study design. The Communications Model of Pain (Hadjistavropoulos & Craig, 2002), which addresses the subtleties of pain expression and communication, will serve as the guiding framework for the proposed feasibility study.

Within an overall theoretical framework for understanding pain assessment, Hadjistavropoulos and Craig (2002) derived a model of human communication that incorporates both self-report and observational measures of pain. The Communications Model is an appropriate theoretical framework for the proposed research study, as the communication of pain is critical to pain assessment and subsequent treatment. The authors derived the Communications Model from Prkachin and Craig's (1995) model to assist in understanding complex social interactions between persons with pain and their caregivers. This latter model was itself a derivation of Rosenthal's (1982) conceptualization of non-verbal communication. Prkachin and Craig proposed an A→B→C model focused on facial displays of pain, where (A) is the experience of an internal state that may be (B) encoded into expressive behavior allowing the observer to (C) draw inferences about the nature of the sender's experience. Hadjistavropoulos and Craig broadened this model to include verbal and non-verbal communication. In their A→B→C model, (A) represents nociceptive or neuropathic pain processed in the brain and experienced as pain, (B) represents the encoding of pain into either verbal or nonverbal behavior, and (C) represents the potential for this behavior to serve as a message that an observer can decode (see Figure 1-1).

The main empirical indicators derived from this model include self-report of pain, the social context of behavior, and observational measures of nonverbal behaviors. Self-report measures are verbal reports that reflect an individuals' subjective description of the

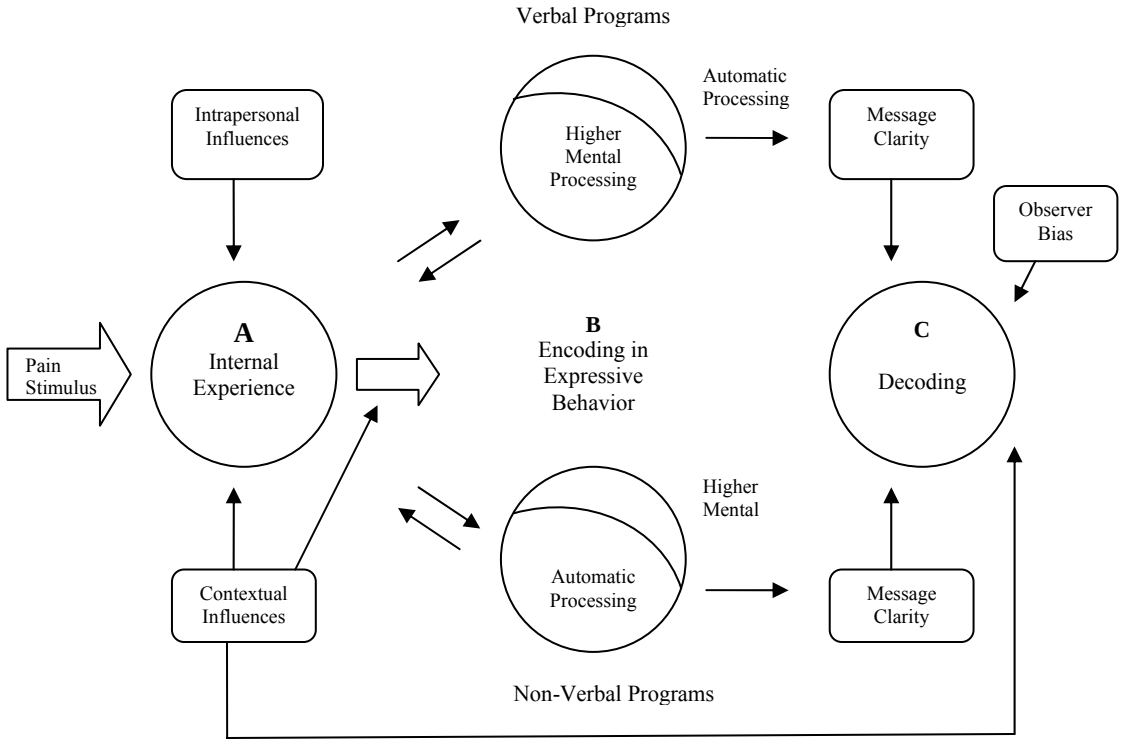


Figure1-1. Communications model of pain (Hadjistavropoulos & Craig, 2002)

experience of pain. The social context of behavior reflects whether this social transaction is instigated by the individual in pain or if it is in response to another's query. Hadjistavropoulos and Craig (2002) point out that the effectiveness of this social transaction can depend as much upon respondent characteristics as upon the nature of the message itself.

For persons with cognitive impairment, self-report measures of pain may not be the most effective way to communicate their pain experience. Rather, observational measures of nonverbal pain (such as facial behavior, limb and torso movements, and changes in habitual patterns of daily living), which focus on signs of pain that are often involuntary and nondeliberate, are more appropriate. One of the key concepts behind this model is that it recognizes that observational measures of automatic expressive behaviors, which focus on involuntary, publicly observable signs of pain, are preferred for

measuring pain when the capacity for self-report of subjective experiences is either not available or when the veracity of self-report is doubted (Hadjistavropoulos & Craig, 2002, p. 553). The authors suggest that this nonverbal behavior usually can be seen as automatic in the sense that the "behavior represents stereotyped, reflexive patterns of response to actual or impending tissue damage that are outside immediate conscious awareness or voluntary control" (p. 553).

For the purpose of this feasibility pilot study, designed to measure the effectiveness of an analgesic drug trial in reducing pain and its associated excess disabilities, the presence of chronic osteoarthritic pain in conjunction with normal daily activity will serve as the pain stimulus. Potential influences (including intrapersonal, cultural, and contextual factors) on the expression of pain are no less relevant in persons with dementia than in cognitively intact older adults, and previous research has found that nonverbal pain expressions do include manifestations of affective qualities of the pain experience (Hadjistavropoulos & Craig, 2002) (A, in Figure 1-1). The encoded verbal and nonverbal expressions of the pain experience (B, in Figure 1-1) will then be decoded by the primary caregiver and the trained observer in order to evaluate the effectiveness of the analgesic drug trial (C, in Figure 1-1). Caregivers and the trained observer will also decode the expression of excess disabilities of untreated chronic pain such as depression, declines in functional performance, sleep disturbances, agitation, and behavioral disturbances in order to observe the effect the analgesic trial had on these outcomes.

Given the complexities of the pain experience and the issues of validity concerning self-report in persons with dementia, self-report measures alone cannot be expected to capture the full spectrum of the pain experience. This is why Hadjistavropoulos and

Craig (2002), incorporate behavioral observations to assess pain in persons with cognitive impairment. Observer reports in conjunction with participant self-report offer the most comprehensive model of pain assessment for persons with dementia. By identifying pain, this model will aid with pain control because the effect of an intervention can be evaluated through subsequent pain assessments following its implementation. Assistance with pain control is needed the most by people who are vulnerable and dependent upon others for generalized care, including persons with dementia. However, caregivers must rely on the availability of reliable and valid information concerning the nature of the individual's distress in order to provide aid, which through this model, can be obtained through behavioral observations. Therefore, the Communication Model will guide the proposed study because it addresses both self-report and observational measures of pain, recognizes the limitations of using self-report measures alone in persons with dementia, and supports a multidimensional approach incorporating observational measures. Specific theoretical constructs, study constructs, and operational definitions are presented in Table 1-1.

Statement of Problem and Study Specific Aims

As mentioned previously, because pain is so prevalent among older adults, and because older adults with cognitive impairment have compromised ability to reliably self-report their pain, the use of observational strategies for pain assessment in this population is warranted. The use of an acetaminophen trial in this population for pain control is well supported in the literature and thus will serve as the tool for assessing the specificity of observational pain measures. The Communications Model serves as a suitable theoretical framework for designing studies aimed at assessing pain through self-report and

Table 1-1. Theoretical and Study Constructs

Theoretical Constructs	Study Constructs	Operational Definitions
Non-Verbal Programs (Observed Pain)	Pain -Caregiver reports of pain	-Sum score of PADE Part 1: Physical (observable facial expression, breathing pattern, and posture); and Part 2: Global assessment of overall pain
	-Trained Observer reports of pain	-Sum score of PADE Part 1: Physical (observable facial expression, breathing pattern, and posture); and Part 2: Global assessment of overall pain
	-Behavioral observation of pain	-Total number of pain behaviors observed during a video-taped activity protocol
	Pain related excess disabilities -Functional performance	-Sum score of PADE Part 3: Functional (ADLs)
	-Behavioral disruptions	-Total and subgroup scores on RMPBC for memory-related problems, depression, and disruptive behaviors
Verbal Program (Self-reported pain)	Pain -Self-reported pain	- average scores on the NRS

PADE: Pain Assessment for the Dementing Elderly
ADLs: Activities of Daily Living, including dressing, feeding oneself, and transfers
RMPBC: Revised Memory and Problem Behavior Checklist
NRS: Numeric Rating Scale

observational measures, and for examining the effect of an analgesic trial on reducing pain behaviors and excess disabilities related to untreated chronic pain. Therefore, in order to examine the effectiveness of an acetaminophen drug trial in persons with dementia, this study has 4 specific aims.

Aim 1: To investigate the effects of the scheduled administration of acetaminophen (1.3 grams up to three times per day) on self-reported pain intensity and the number of observable pain behaviors exhibited by persons with dementia.

Hypothesis: Regular administration of acetaminophen will decrease the total number of observable pain behaviors (as rated by the caregiver and trained observers) exhibited by the participant, but will have no effect on self-reported pain intensities.

Aim 2: To investigate the effects of the scheduled administration of acetaminophen on the frequency and severity of excess disabilities of pain in persons with dementia.

Hypothesis: Among persons with dementia, the frequency and severity of excess disabilities of pain, such as depression, agitation, sleep disturbance, behavioral disturbances, and impaired functional performance will decrease from baseline after implementing regular administration of acetaminophen.

Aim 3: To determine the reliability of informal caregiver ratings' of the frequency of pain behaviors and excess disabilities exhibited by persons with dementia.

Hypothesis: After an initial training session, informal caregivers will display moderate to good reliability with a trained observer in ratings of the frequency of pain behaviors and excess disabilities.

Aim 4: To determine the most frequent behavioral indicators of pain displayed by persons with dementia.

Hypothesis: Based on findings from similar studies, the most frequently displayed behaviors indicative of pain are expected to be guarding, rubbing, shifting and bracing (Keefe & Block, 1982; Horgas & Elliott, 2005).

CHAPTER 2
REVIEW OF THE LITERATURE

The following discussion will demonstrate how this proposed study will build on the information gathered by previous researchers in an effort to explore the effects of a pain treatment regimen on observable pain behaviors in persons with dementia. In order to understand the necessity of this treatment regimen, it is important to first understand the path laid by previous researchers that supports the need for this study. First, the degree to which pain afflicts both cognitively intact and impaired older adults will be reviewed. Second, the validity of emerging strategies for pain assessment in cognitively impaired older adults will be discussed and analyzed in relation to the more traditional pain assessment strategies for cognitively intact older adults. Included in this discussion will be an overview and definitions of the term "pain behaviors" as well as a section describing the use of informal caregivers as proxy raters. Third, excess disabilities related to untreated and undertreated chronic pain will be explored in order to highlight the need for effective pain management in this population. Fourth, current pain management guidelines for older adults will be discussed, followed by a review of studies highlighting inadequate pain management in persons with cognitive impairment. The proposed study will fill a gap in the existing literature by beginning to investigate pain treatment in cognitively impaired elders.

Pain Prevalence

Adults ages 65 and over continue to constitute the fastest growing segment of society. Because the number of conditions an individual may develop with pain as a

symptom or outcome increases with age, it is appropriate that pain assessment in this population receive attention from both medical and research communities. The prevalence of pain in this population is most often attributed to the presence of chronic musculoskeletal conditions that are common in this age group. A 1998 study conducted by Horgas and Tsai found musculoskeletal conditions, such as arthritis or osteoporosis, to be the most frequently diagnosed painful conditions among nursing home residents. Herr (2002) states that "osteoarthritis alone may be a source of chronic pain in as much as 80% of the population older than age 65" (p. 21).

Weissman and Matson (1999) estimate that 80% of community dwelling elderly have at least one chronic disease, that 70% experience some type of pain, and that only 18% take pain medication for chronic pain. Huffman and Kunik (2000) found that 86% of rural community dwelling older adults had pain during the previous year and 59% reported multiple pain complaints. In a study specifically comprised of community-dwelling persons with dementia, only 32% self-reported having current pain (Shega, Hougham, Stocking, Cox-Hayley, & Sachs, 2004), whereas Mitchell, Morris, Park, and Fries (2004) found that 53.4% of their community-dwelling sample with dementia receiving terminal care were experiencing daily pain. Several researchers have found that anywhere from 45% to 83% of elderly residing in nursing homes experience some type of pain (Blomqvist & Hallberg, 1999; Horgas & Dunn, 2001; Weissman & Matson). Ferrell, Ferrell, and Osterweil (1990) found that as few as 29% of a sample of nursing home residents reported having no problems with pain, while 24% reported having constant pain.

Pain Assessment

With such a high prevalence of pain in older adults, it is necessary to have successful methods of assessing painful conditions in order to provide individuals with appropriate treatment. This is important because untreated chronic pain may lead to excess disabilities such as impaired physical and social functioning, lowered quality of life, and/or depression (Parmelee, 1993). Eliciting an individual's self-report is the most common method of pain assessment. However, Ferrell, Ferrell, and Rivera (1995) found that approximately 65% of nursing home residents have a specific barrier to the ability to self-report pain due to the presence of cognitive deficits or mental illness. Thus, it is important to consider multiple approaches to assessing pain.

Self-Report

Several tools exist for measuring self-reported pain, such as the visual analog scale (VAS), the verbal descriptor scale (VDS) and the numeric rating scale (NRS), and research has consistently "supported the use of simple, self-report pain rating scales for chronic pain patients" (Chinball & Tait, 2001, p. 173). Both the VDS and NRS have been shown to be reliable and easy to use with an elderly population (Gagliese & Melzack, 2003; Herr & Mobily, 1993). Typically these scales are presented either vertically or horizontally with values ranging from 0-6, 0-10, or even 0-100, where 0 represents no pain and the highest number represents worst possible pain. When specific questions about pain are presented, the individual is asked to choose a number on the scale that most accurately reflects this pain.

However, there are several factors that may complicate pain assessment in older populations and consequently question the validity of self-reports. In cognitively intact older adults, these factors include a tendency for older adults to under-report pain, either

because they diminish the importance of mild pain and attribute pain to the normal aging process (Gagliese & Melzack, 2003; Gibson & Helme, 1995) or because they fear what an intensification of painful symptoms might mean (i.e. worsening of a disease process, need for diagnostic testing, or impending death) (Herr, 2002). Older adults may also underreport pain in an effort to maintain a positive self-concept. It is also important to consider that the manner in which a person responds to pain is highly individualized and the impact pain will have depends on both objective indicators of its severity and stressfulness, as well as how it is interpreted for personal meaning (Markus & Herzog, 1991).

In cognitively impaired individuals, the factors that complicate the use of self-report are vastly different. Snow, Rapp, and Kunik (2005) report that in order to accurately self-report the presence of pain, one must possess the ability to "understand the question in a pain rating, recall pain events in the given time frame, (and) accurately interpret the experience of noxious stimuli as painful events" (p. 22). Communication disorders including reduced receptive and expressive language exacerbate cognitively impaired individuals' inability to report pain (Chinball, Tait, Harman & Leubbert, 2005). Supporting this fact is the finding that chronic pain is less likely to be identified among cognitively impaired nursing home residents than more alert individuals (Sengstaken & King, 1993). It is not clear whether the decreased self-report of pain in persons with dementia is due to actual less pain or a lessened ability to report such pain (Huffman & Kunik, 2000). In either case, measuring pain with self-reports in this population may be unreliable due to the deficits inherent to dementia. Such deficits include compromised cognitive and verbal skills (i.e. memory loss, loss of judgment, confusion, and attention

and language deficits) making it difficult for persons with cognitive impairments to recall and/or express pain. These deficits not only affect pain assessment in this population, they also may constrain the ability to assess the effectiveness of pain interventions in that persons with dementia may not be able to reliably report a decrease in pain either, thus potentially leading to further undertreatment of pain in this population. (Chinball et al., 2005).

However, it should be mentioned that some researchers have supported the use of self-report in this population. Ferrell et al. (1995) found that at least 83% of nursing home residents were able to successfully use at least one self-report pain scale, even though the study participants' average Mini Mental State Exam score was 12, indicating moderate to severe cognitive impairment. Parmelee (1994) reported that "when questions are phrased simply and straightforwardly, even moderately demented individuals can give valid, reliable information about their pain experience" (p. 289). In a recent study, Pautex and colleagues (2005) found that only 12% of their hospitalized participants with dementia did not understand any one of the four self-report scales they were administered. However, these authors caution that "the ability to complete an assessment does not imply reliability" (p. 527). Because of the conflicting opinions as to the validity of self-report in persons with dementia, it stands to reason that, while it should not be automatically dismissed in this population, neither should self-report be the sole method of pain assessment. Alternative strategies for assessing pain in the cognitively impaired have been the recent focus of research for several investigators. These strategies have revolved around assessing objective behavioral manifestations of pain, and since a majority of persons, even those with dementia, were able to use at least one self-reported

pain scale, these scales can serve as useful measures against which to compare observational strategies.

Observational Strategies

If we were to accept McCaffery and Beebe's (1989) definition that pain is "whatever the patient says it is and occurs whenever the patient says it does," we would have to conclude that if a person does not verbally express that they are in pain then they must not have pain. Marzinski (1991) argues that this definition cannot be used with the nonverbal elderly (including those with dementia) and that behavioral assessment is the only acceptable way of assessing pain in this population. Also, since the use of self-report indices of pain requires verbal skill and comprehension, it is necessary to focus on these alternative measures of pain in persons with compromised verbal abilities. Therefore, to assess pain in persons with dementia, researchers have begun to focus on automatic, less verbal, pain displays. Weissman and Matson (1999) support this focus by finding that in moderately to severely cognitively impaired persons, discomfort is often non-verbally exhibited. The rationale for using observable behaviors as representative of pain is appropriate because observational measures of pain capture behavior that is more automatic and less subject to voluntary control, in contrast to self-reports of pain which require higher mental processes and may be more susceptible to purposeful distortion (Hadjistavropoulos & Craig, 2002). This is appropriate for persons with cognitive impairment, where unlike with verbal abilities, there is no barrier to automatic processes.

Keefe and Block (1982) were among the first researchers to use direct observation of pain in their work involving patients with chronic low back pain. Their observation methodology consists of instructing the patient to "engage in a standard set of daily activities designed to elicit pain behavior" (Keefe & Smith, 2002, p. 118). The authors

observed for the following five overt behaviors that were thought to be consistent with chronic pain: guarded movement, bracing, rubbing the affected area, grimacing, and sighing. Through a series of experiments, these behaviors were shown to be highly reliable and to have good construct, concurrent, and discriminant validity. Thus, this work established several important components of observational methods: 1) pain behaviors can be reliably recorded by trained observers, 2) the frequency of pain behaviors correlates with the patient's own self-report of pain, and 3) naïve observers' ratings of pain also correlate with the frequency of pain behaviors.

Through the success of this work, a person's observable pain behaviors have become essential to understanding the experience and impact of pain (Keefe & Smith, 2002). Because these methods were developed in verbal, cognitively intact populations who can also self-report pain, it is clear that the observation of pain behaviors is crucial to pain assessment in persons with dementia who have compromised cognitive and verbal skills, such as memory loss, loss of judgment, confusion, and attention and language deficits, making it difficult to recall and/or express pain.

Advantages of observational methods

There are several advantages to using observational methods to assess pain in persons with dementia. These observations are "more objective and accurate measures than can be obtained through anecdotal observation" (Keefe & Smith, 2002, p. 123). Another advantage is that it allows the researcher or clinician to directly observe pain behaviors as well as the effects of chronic pain interventions by comparing the frequency of pain behaviors before and after the implementation of the intervention. If an intervention is an effective pain reliever, the frequency of observable pain behaviors will decline after its implementation. Additionally, another advantage of observational

methods is that the researcher can make alternative treatment decisions if intervention is ineffective.

A major design advantage of objective methods is that they allow the researcher to precisely measure the effects of social, psychological, or environmental factors that may influence chronic pain. Keefe and Hill (1985) found pain behaviors to be more likely to occur when patients were moving, such as during walking or transferring from one position to another. Consequently, their research plan included having participants perform an activity-based protocol in order to ensure maximum likelihood of observing pain behaviors. Furthermore, Keefe and Smith (2002) maintain that for persons with musculoskeletal problems (e.g. arthritis), performing daily tasks such as sitting, standing, walking, and reclining for 1-2 minute periods is capable of eliciting pain behavior. Finally, and perhaps most importantly to the proposed research study, observational methods of pain assessment allow a researcher to gather reliable and valid pain (and pain intervention) information in populations whose verbal report of pain is compromised and unreliable, such as is the case for persons with dementia.

Limitations of observational methods

Despite the apparent utility of observational methods to assess pain in persons with dementia, there are limitations. One limitation is the potential for reactivity (i.e. the tendency for the participant to alter behavior in the presence of an observer) (Elder, 1999; Keefe & Smith, 2002). Due to cognitive decline, persons with dementia are less likely to consciously alter their behavior than are cognitively intact persons (Hadjistavropoulos & Craig, 2002). The potential for observer bias is another limitation of observational methods. Keefe and Smith suggest that this limitation can be minimized by carefully

training observers, conducting frequent reliability checks, and holding periodic retraining sessions.

Pain Behaviors

Measuring pain behaviors in nonverbal persons through direct observation can yield otherwise unobtainable information about an individual's experience of pain. In order to use the term *pain behaviors* as an outcome measure, it must first be operationally defined in terms of its use in the study. To operationally define *pain behaviors* and select appropriate measurement tools to fit the study's guiding theory and research questions, other researchers' definitions and measures of *pain behaviors* must be reviewed. Pain behaviors have been defined as "verbal or nonverbal actions understood by observers to indicate that a person may be experiencing pain and suffering" (Loeser, 2001, p. 19). Specifically, these actions include, but are not limited to, audible complaints, facial expressions, abnormal postures or gait, use of prosthetic devices, avoidance of activities, overt expressions, and verbal or nonverbal complaints of pain, distress, and suffering. This definition captures the most frequently recognized behaviors thought to signify pain and serves as a basis from which other researchers can select the most appropriate behaviors to study pain in their population of interest.

All definitions of pain behavior recognize them to be observable, nonverbal behaviors that signify pain to others (Cohen-Mansfield & Creedon, 2002; Keefe & Block, 1982). However, behavioral observation studies differ in their selection of the actual behaviors they choose to study in their population of interest. Fordyce (1976), who popularized the study of chronic pain behaviors, proposed that a thorough behavioral analysis could be just as important as a medical evaluation for evaluating chronic pain and proposed identifying the following as pain behaviors: the report of pain, low levels of

activity, taking pain medications, body posturing, and facial expressions (as cited in Keefe, 1982). Subsequent research studies have followed one of two paths; either they are designed to conduct a comprehensive behavioral analysis or they are designed with a specific set of pre-identified behaviors and measures to identify pain.

Identifying Pain Behaviors

Cohen-Mansfield and Creedon (2002) further developed the definition of *pain behavior* by interviewing nursing home staff regarding specific behaviors they thought were associated with resident pain. The resulting core group of behaviors was categorized into the following four categories: specific physical repetitive movements (i.e. facial expressions and body postures), vocal repetitive behaviors (i.e. moaning, crying, or screaming), physical signs of pain (i.e. skin discoloration, swollen joints, or a change in vital signs), and changes in behavior from the norm for that person (i.e. changes in mood, movement, or eating patterns). The authors also found that nursing home staff rated vocalizations, rubbing the affected area, and reluctance to move to be among the most prevalent resident pain behaviors. This work led them to develop the following working definition of pain as it applies to evaluating pain behaviors in persons with dementia: "pain is suffering associated with bodily injury or disease, characterized by physical and/or emotional discomfort, which gives rise to a set of distinctive behaviors perceived by caregivers as indicative of that discomfort" (p. 65). Alternatively, Weiner, Peterson, and Keefe (1999) found other salient pain behaviors in nursing home residents (on which residents and caregivers agreed) to be the use of mechanical help, shifting weight when seated, taking or asking for pain medication, moving or walking in a protective fashion, moving extremely slowly, limping, lying down, bracing when seated,

clutching the painful area, stiffness, and asking someone to do something to help the pain.

Testing Pre-identified Behaviors

Rather than conducting a comprehensive behavioral analysis, other researchers have tested the ability of specific behaviors to signify pain. Keefe and Block (1982) observed for specific behaviors in persons with chronic low back pain by having them perform an activity-based protocol (consisting of activities of daily living) as a pain stimulus. The behaviors they hypothesized would signify pain included: guarded movements, bracing, rubbing, grimacing, and sighing. Not only did the authors find that they could reliably observe these behaviors, but the frequency of these behaviors correlated with patients' self-report, decreased with treatment, were observable by naïve observers, and discriminated persons with chronic low back pain from normal and depressed controls.

Hadjistavropoulos and colleagues (1998), in an effort to develop an observational strategy to assess pain in persons with dementia, investigated facial reactions to pain using a combination of the extensively tested and well-validated Facial Action Coding System (FACS), nurses' ratings, and student volunteers' ratings. They discovered that facial reactions, especially brow lowering and chin raise, were useful indicators of pain in this population whether rated by FACS trained observers, nurses, or students.

Observing pain behaviors can also provide daily documentation of the effects of a pain management program (Keefe & Smith, 2002). Because pain behaviors are readily observable and recordable by trained observers, an observational method of pain assessment is a reasonable way to assess pain in a nonverbal or unreliable population, such as those with cognitive impairments. Researchers have begun to study behavioral

assessments by taking these behaviors identified as indicative of pain in cognitively intact older adults and then applying these to cognitively impaired older adults with promising findings (Hurley et al., 1992; Villanueva et al., 2003; Warden et al., 2003). Often in research studies using observational methods to assess behavior, participants are videotaped so that these behaviors may be coded at a later time (Keefe & Block, 1982; Keefe, Crisson, Maltbie, Bradley, & Gil, 1986).

In a study conducted by Hurley and colleagues (1992), the authors argue that persons who have lost the cognitive capacity and verbal ability required to communicate must rely on nursing staff and/or other caregivers to recognize, assess, and treat their pain. However, how can these caregivers perform such a task without the knowledge of what they should be looking for to indicate pain in their care recipients? This is why these researchers have focused on behaviors commonly found in people with dementia of the Alzheimer's type who have pain. These behaviors include facial expressions, body movements, certain postures and gestures, and vocalizations. The authors showed that these observed behaviors served as useful external indicators of what the person with dementia experienced internally. Although researchers have begun to make strides in identifying useful ways of assessing pain in persons with dementia, there still exists a critical underassessment of pain in this population leading to large quantities of untreated and undertreated pain. To help abate the chasm, the American Geriatrics Society (2002) put forth a comprehensive framework regarding behavioral indicators of pain. The framework recognizes the following 6 main types of pain behaviors/indicators: facial expressions, verbalizations/vocalizations, body movements, changes in interpersonal reactions, changes in activity patterns or routines, and mental status changes.

Underassessment and Treatment of Pain in Persons with Dementia

It has been recognized that assessing pain in persons with dementia presents specific challenges, and as a result underassessed and undertreated pain is an unfortunate reality for many people with dementia. An estimated 4.5 million people in the United States have dementia of the Alzheimer's type; this number is expected to grow to approximately 16 million by the year 2050 (Carter, Rose, Palesch, & Mintzer, 2004). Furthermore, 50% of older adults over age 85 have Alzheimer's disease with 28% of this population having severe disease (Herr, Bjoro, & Decker, 2006). With prevalence rates of pain in older adults ranging from 45-83% and with no reason to assume that people with dementia experience less pain, it is critical to assess the amount of treatment for pain this population receives. Some factors that may contribute to this inadequate pain assessment and treatment in the healthcare environment are due to "the presence of comorbidities that compete for attention of healthcare staff, a tendency for observers to discount high levels of reported pain, physician fears regarding drug use for pain, and nurse expectations about pain coping…each of these factors is magnified with respect to cognitively impaired older patients" (Chibnall & Tait, 2001, p. 173-4).

Several researchers have demonstrated that cognitively impaired individuals receive lower amounts of medication for pain treatment. Horgas and Tsai (1998) found that "nursing home residents with cognitive impairments are less likely to be prescribed and administered pain drugs and receive lower dosages of analgesics when medicated than are their more cognitively intact peers" (p. 240). Also, they found that while 87.6% of participants were prescribed at least one pain drug, only 47% were given an analgesic during the course of their study. Of these drugs, mild analgesics were most commonly prescribed (80%) with acetaminophen being the most frequently prescribed analgesic

(59.6%). Chibnall and Tait (2001) found that 61% of cognitively intact elders were prescribed a nonsteroidal anti-inflammatory agent (NSAID) as compared to 48.5% of cognitively impaired elders. Morrison and Siu (2000) found that when "as needed" analgesics are ordered in the elderly, "only 24% to 27% of the prescribed doses are actually administered; this percentage declines with advancing age" (p. 241). Additionally, Pautex and colleagues (2005) found that approximately one-quarter of hospitalized persons with dementia who self-reported pain were not receiving any analgesia. It is imperative that these treatment disparities be overcome. These disparities in pain treatment continue to exist despite the advances made in assessing pain in persons with dementia. Thus, educating those that care for persons with dementia about proper pain assessment and treatment is a crucial component to obtaining appropriate pain management outcomes in this population.

Caregiver Assessments

According to the Alzheimer's Association and the National Alliance for Caregiving (2004), there are 8.9 million caregivers in the United States caring for someone 50 years or older with dementia. Considering that pain control is "one of the least well managed aspects of professional medical care (and that) untrained family caregivers are routinely given the responsibility of managing pain at home," it is imperative that these caregivers, who have the most day-to-day contact with persons with dementia, possess the skills to assess, treat, and reliably report the pain that the individual experiences (Levine, Reinhard, Feinberg, Albert, & Hart, 2003, p. 20). While many researchers have developed assessment tools and strategies that have proven to be successful and reliable in detecting pain in this population, not all of these tools and strategies are easily implemented or taught to caregivers. In fact in most observational studies, data are coded

(either in real-time or from videotaped sessions) by trained research assistants. The researchers who developed the Discomfort Scale for Dementia of the Alzheimer Type (DS-DAT) acknowledge that this scale is most useful for research purposes because it requires more time to train for accurate use than is realistic for caregivers (Warden et al., 2003). In order to translate research into practice as well as to test the construct and social validity of observational methods, these methods must be tested by naïve observers (meaning any untrained observer such as a family caregiver, nurse, or nursing assistant) who have the most daily contact with these pain patients. Since caring for persons with dementia is often a time-consuming and stressful job, many caregivers may not have a lot of time to think about assessing the individual's pain. Quick, easily taught, and reliable tools and strategies for caregivers to use to identify pain are needed.

In an effort to create a tool that caregivers could reliably use to assess pain in persons with dementia, Villanueva and colleagues (2003) developed the Pain Assessment for the Dementing Elderly (PADE). This tool was tested by a group of caregivers of persons with dementia in long-term care settings. The tool assesses "facial expressions, activities of daily living, and the caregiver's overall judgment of the resident's pain" (Villanueva et al., p. 2). The researchers found valid and reliable pain assessments with this group of caregivers after a 1-hour training session. Also with practice, caregivers were able to complete the PADE in 5-10 minutes.

Informal Caregivers versus Trained Observers

Several research studies have tested their observational methods with naïve observers and found promising results. Hadjistavropoulos et al. (1998) compared trained observer's ratings with the Facial Action Coding System (FACS) to pain intensity ratings by 10 female nurses and 10 female university students after watching videotaped

reactions of older adults undergoing venipuncture. All three of these measures were found to be significantly correlated with one another, thus lending support to the validity of informal caregivers' (naïve observers') ratings. Likewise, Keefe and Block (1982) asked untrained observers to review videotaped segments and rate subject's pain intensity with three different measures. The total number of pain behaviors (as coded by a *trained* observer) correlated well with all three ratings from naïve observers. Furthermore, Werner, Cohen-Mansfield, Watson, and Pasis (1998) found that family caregivers' and staff members' ratings of senior day care participants' pain severity were highly correlated (r= 0.86).

Informal Caregivers versus Participant Self-Report

In order to rely on caregiver ratings, it is important to trust that their ratings accurately represent what the care recipient would say themselves. Overall, the reliability of naïve observers as proxy raters has not been found to be very strong and even healthcare professionals have been found to be ineffective at both pain assessment and treatment (Herr et al., 2006). Horgas and Dunn (2001) found no significant association between nursing assistants' ratings of resident pain and the resident's own ratings. Pain was also underdetected by nursing assistants for 37.8% of residents. Most of the research studying caregiver ratings has been done within the context of chronic illness, especially cancer. For cancer symptoms, Nekolaichuk, Maguire, Suarez-Almazor, Rogers, and Bruera (1999) suggest that the best assessment and treatment outcomes for cognitively impaired patients may be obtained by selecting caregivers who best understand and represent the patient's experience. These authors also state that both healthcare providers and other significant caregivers tend to overestimate symptoms of depression and anxiety and they underestimate performance status and quality of life. Nekolaichuk et al.,

through a study comparing cancer patients, their family caregivers, and nurses' ratings of patient's symptoms, found that all three respondents were reasonably consistent with one another when ratings were averaged across all symptoms at two measurement times. However, for any one rater on one occasion, reliability estimates were less than 0.70 for most symptoms.

Through a review of studies examining ratings of pain by cancer patients and their caregivers, Lin (2001) found that most studies used correlation statistics which may overestimate the actual relationship because this statistic does not take into account error variance. The studies reviewed tended to show that patient and caregiver ratings were significantly correlated and accurate, with some studies showing a tendency for family caregivers to overestimate, rather than underestimate the patient's pain. In her own study comparing cancer patients' and family caregivers' ratings of pain intensity and interference, Lin found that the Pearson's correlation, intraclass correlation coefficients, and the kappa statistics of interrater agreement were statistically significant, lending more support that the caregiver ratings were accurate representations of the patient's own ratings. However, the author cautions that the kappa values for worst pain (.25), least pain (.18), current pain (.20), and average pain (.25) do not represent good agreement beyond chance and that family caregivers tended to overestimate patient's pain severity.

In a study to identify behaviors signaling pain in nursing home residents, Weiner et al. (1999) also examined the congruence between self-reported resident and caregivers' (nurse and family) ratings of pain behaviors and pain intensity. The authors found that while both the nurse and family caregiver felt similarly confident in their ability to rate the residents' pain, both had poor agreement with the residents' own ratings regarding

identification of pain behaviors and rating pain intensity. Interestingly, over 75% of nurses and only 44% of family caregivers felt that the residents showed their pain outwardly and 71% of nurses felt that cognitive impairment made assessments more difficult. Cremeans-Smith and colleagues (2003) found that 55% of spousal caregivers rated their wife's recent osteoarthritis pain severity in agreement with her own rating. Again, for those dyads who disagreed, the caregiver was more likely to overestimate, rather than underestimate, their spouse's pain severity. In the only study to date studying the congruence between caregiver and patient report of pain in community-dwelling persons with dementia, 59% of the 150 patient-caregiver pairs, agreed on the presence or absence of patient pain. Again, caregivers were more likely to estimate their care recipients' pain severity (Shega et. al, 2004).

There has been no standard set to gauge how accurate caregiver ratings must be in order to be considered as valid proxies. The majority of research utilizing proxy reports from caregivers has shown only moderate agreement with the care recipient, with caregivers tending to overestimate levels of pain and excess disabilities related to chronic pain (such as depression, anxiety, and functional disability) (Cremeans-Smith et al., 2003; DeBettignies, Mahurin, & Pirozzolo, 1993; Lin, 2001; Nekolaichuk et al., 1999; Seltzer & Buswell, 1994; Weiner et al., 1999; Zanetti, Geroldi, Frisoni, Bianchetti, & Trabucchi, 1999). These more negative assessments (i.e. higher ratings of pain intensity) by caregivers have been attributed to the distress and burden they experience when caring for a close relative with dementia, as well as to a greater reported degree of concern over patient disabilities (DeBettignies et al.; Seltzer & Buswell; Zanetti et al.). In situations where relying on caregiver proxies is necessary, they should be seen as reasonably

accurate (Lobchuk, Kristjanson, Degnet, Blood, & Sloan, 1997). While the research in this area demonstrates that caregivers' accuracy in assessing patient symptoms is not in total agreement with care recipients, caregiver report is the best option for assessing pain and its excess disabilities in persons with dementia. And, as has been shown, although caregivers' ratings are not perfect, they tend to err on the side of overestimating rather than underestimating the patients' own ratings. However, it should be noted that most of the studies that asked caregivers to give proxy reports for the care recipient did not base this proxy report on direct observations of the care recipient, but rather on global perceptions.

Among the many factors that may contribute to caregivers' inability to report accurate proxy ratings, the most important to consider is the tremendous stress and burden that caregivers of persons with dementia are under. Many of these caregivers are themselves elderly, 63 being the average age of caregivers caring for someone age 65+, and one-third of these caregivers are in fair to poor health (Administration on Aging, 2004). Caregivers are at risk for "burnout" as the average person with dementia requires 69-100 hours of care each week (Kahn et al., 1998). Often behavioral disturbances in persons with dementia result in high levels of caregiver burden and are frequently a precipitant to nursing home placement (Kahn et al.; Lantz, 2003). Czaja, Schulz, Lee, and Belle (2003) found that functional limitations and behavioral problems of the care recipient were the primary stressors for the caregiver. This is especially true for caregiving wives, who are more likely to experience caregiving distress and report more frequent problem behaviors in their spouse than caregiving husbands (Ingersoll-Dayton & Raschick, 2004). Some researchers have proposed that these behavioral disturbances and

functional limitations may be related to untreated chronic pain (Buffum, Miaskowski, Sands, & Brod, 2001; Douzjian, Wilson, Shultz, Tapnio, & Blanton, 1998; Ferrell, 1995; Gibson & Helme, 2000; Lantz; Kahn et al.; Villanueva et al., 2003). Therefore, it is necessary to educate caregivers in both the importance of, and strategies to, assess and treat pain in their care recipients.

Strategies to Strengthen the Validity and Reliability of Caregiver Report

The first step in overcoming methodologic problems related to proxy report is by using observational methods (either in combination with the caregiver report or training the caregiver to observe care recipient behavior). There are also strategies to help increase the reliability of caregiver ratings. An initial strategy is to have the caregiver be the person who best understands and represents what the care recipient experiences; this would most likely be the primary caregiver who lives with and is most familiar with the care recipient (Bohac, McNeilly, & Folks, 2003; Nekolaichuk et al., 1999). The most useful way to increase untrained observers' ratings is through education and training. Training does not have to be as intense as is required for formally trained observers. For example, when creating the Pain Assessment for the Dementing Elderly tool, Villanueva and colleagues (2003) obtained valid and reliable caregiver pain assessments after a 1-hour training session. Researchers should also educate caregivers to time their observations with potentially painful events in order to maximize the potential for observing pain behaviors (Weiner et al., 1999). Bohac and colleagues suggest increasing caregiver familiarity with the research instruments being used (with practice sessions) to ensure greater reliability and validity of caregiver reports. Finally, as mentioned previously, caregiver reports have been shown to be influenced by the amount of burden and distress the caregiver feels. Perhaps a strategy aimed at decreasing caregiver burden

and distress would in turn, positively influence the reliability and validity of their reports of care recipient behavior.

Excess Disabilities related to Dementia and Chronic Pain

Investigators whose research focuses on persons with dementia are well aware of the excess disabilities (behavioral disturbances) that accompany disease progression. Research in this area can hardly be conducted without acknowledging the complex behavioral problems that accompany this disease (Teri et al., 1992). Lantz (2003) reports that 65% of community dwelling older adults with dementia have at least one disruptive behavior and 40% have three or more. Rowe, Straneva, Colling, and Grabo (2000) found that 86% of persons with dementia evaluated at a community-based clinic had at least one disruptive behavior, with 86% being verbally agitated, 55% being physically agitated, 33% being verbally aggressive, and 21% being physically aggressive. Overall, the behavior problems commonly recognized to be associated with dementia include: depression, agitation, aggression, anxiety, delusions, impulsivity, repetitive actions, restlessness, disinhibition, resistiveness, physiological risks, impaired cognitive function, difficulties with performance of activities of daily living (ADLs) and instrumental activities of daily living (IADLs), pacing, vocalizations, altered sleep routines and time spent in bed, wandering at night, altered social behavior, and increased health care utilization and costs (Albert, et al. 2001; Ancoli-Israel et al., 2003; Herr et al., 2006; Hinton, Haan, Geller, & Mungas, 2003; Kahn et al., 1998; Lantz, 2003; Opie, Doyle, & O'Connor, 2002; Teri et al). Furthermore, Logsdon, Gibbons, McCurry, and Teri (2002) report that caregivers for persons with severe dementia (MMSE <10) reported higher rates of disruptive behaviors and worse physical functioning in their care recipients.

The presence of these behavioral problems and limitations in functional performance is a source of stress and burden to the caregiver. Also, behavioral problems in this population can negatively influence quality of life as well as lead to increased social isolation and risk of falls (Horgas & Margrett, 2001). While previous researchers have targeted reducing these outcomes with interventions such as light therapy (Ancoli-Israel et al., 2003), psychosocial and behavioral interventions (Czaja et al., 2003), or administration of psychotropic medications (Opie et al., 2002), other researchers have found more promising results by assessing and treating underlying chronic pain (Douzjian et al., 1998; Opie et al.). The rationale for this approach stems from the observation that many of the behavioral problems and functional limitations that afflict persons with dementia are also seen in cognitively intact persons who experience chronic pain. For instance, Vlaeyen, Van Eek, Groenman, & Schuerman (1987) identified nine components of chronic pain behavior: anxiety, attention seeking, verbal pain complaints, medication use, general verbal complaints, distorted posture and mobility, fatigue, insomnia, and depressive mood. Ferrell (1995) classifies depression, decreased socialization, sleep disturbances, impaired ambulation, and increased health care use and costs as complications from untreated chronic pain. Thus, there is considerable overlap between excess disabilities related to dementia and those related to chronic pain.

Ferrell (1995) emphasizes that in order to maximize mobility and independence, health care providers and caregivers need to assess ADLs because evaluating functional status is an important measure of the success of pain management. Studying pain from osteoarthritis (OA) in rural adults age 45 and older, Jordan, Linder, Renner, and Fryer (1995) found that hip OA, hip pain, knee OA, and knee pain were all associated with self-

reported and observed limitations in functional performance. Even the American Geriatrics Society's panel on persistent pain in older adults recommended in 2002 that recent changes in function, verbalizations suggestive of pain, and nonverbal pain behaviors should be assessed in all chronic pain patients. For those with dementia, caregiver reports should be solicited.

Several researchers have begun to study the link between pain and specific problem behaviors in persons with dementia. Buffum et al. (2001) found significant positive correlations (r= .50, *P*= .003) between measures of discomfort (Discomfort Scale) and agitation (Cohen-Mansfield Agitation Inventory) in nursing home residents with dementia, suggesting that agitated behaviors could indicate painful sensations. The authors suggest that although the correlation was strong, the discomfort behaviors may be related to other things, such as hunger or being wet from urinary incontinence, and the best way to evaluate the role of pain in prompting these behaviors would be to administer an analgesic and then observe for changes in behaviors. Three groups of researchers have done this. In an effort to reduce challenging behaviors in nursing home residents with dementia, Opie et al. (2002) initiated 4 distinct groups of interventions: psychosocial strategies, nursing approaches, psychotropic medications, and management of pain. Interventions were tailored to each of the 99 participants, with the majority receiving more than one intervention. Changes in pain management were recommended for 18 participants, and while the authors do not report the effects of pain management alone in reducing challenging behaviors, overall their intervention strategies showed a statistically significant improvement in the target behaviors of restlessness, physical aggression, verbal disruption, and inappropriate behavior. The limitation of this study is that the

effect of any one intervention on reducing challenging behaviors is unknown; however, their results argue that individually-tailored interventions are effective in reducing challenging behaviors in persons with dementia.

Another group of researchers was able to show a strong relationship between treating pain and decreasing problem behaviors. Douzjian et al. (1998) observed that demented residents who were admitted to a skilled nursing facility (SNF) after being discharged from the hospital were often receiving antipsychotic medications without having any documented psychological history. Since the use of antipsychotic medications is strictly regulated in SNFs, they hypothesized the residents' behavior may be linked to pain, so the authors devised what they term an "informal study" by trying to initiate a pain treatment regimen to replace the use of antipsychotic medications. Eight residents were placed on a pain treatment regimen of acetaminophen 650 mg three times a day. Five (63%) of these residents showed a decrease in the number of problem behaviors and the staff was able to discontinue four orders for antipsychotic drugs and two for antidepressants. Most impressively, the authors were able to decrease the facility's use of antipsychotic drugs from 20% to 0% over the study period. This is clinically significant because antipsychotic drugs often work inconsistently and can lead to adverse events such as a higher risk for falls (Opie et al., 2002).

In perhaps the most promising study to date, Chinball and colleagues (2005) found that 4 weeks of acetaminophen (3,000 mg/d) was more effective than placebo in increasing participants' engagement with their environment. Specifically, while taking the acetaminophen, participants spent significantly more time in "social interactions, engaged with media, talking to themselves, engaged in work-like activity, and

experiencing unattended distress…and spend less time in their rooms, less time removed from the nursing home unit, and less time performing personal care activities" (p. 1921). However, there was no effect of acetaminophen on agitation, emotional well-being, or as needed psychotropic medication use. Similarly, Allen and colleagues (2003) also found that nursing home residents who had received analgesic medication during the course of their 4-week study were more active than those who did not receive any analgesia.

Pain Management and Treatment Guidelines

Now that researchers have begun to demonstrate successful ways to assess pain in persons with dementia and a correlation between chronic pain and behavioral problems, the next logical step is to further examine pain treatment strategies in this population. Treatment guidelines for the general population with chronic mild to moderate pain state that nonpharmacologic strategies are the appropriate first line defense. These strategies include patient education, self-management programs, and exercise, among others. For obvious reasons, these strategies are not appropriate for persons with impaired memory function. The American Geriatrics Society's 2002 Management of Persistent Pain in Older Adults state that analgesic drugs are safe and effective for use by older people. They recommend following the adage "start low and go slow" in order to assess each individual's response to a given medication. The guidelines report that for most patients "with persistent mild to moderate musculoskeletal pain respond favorably to around-the-clock doses of acetaminophen" (p. S213). This is advantageous because this treatment is capable of providing satisfactory pain relief and has a much lower risk of side effects than NSAID drugs. The maximum dosage for acetaminophen in these guidelines is 4000 mg/24 hours, with 4-6 hour dosing (not to exceed a daily amount of 4 grams), recognizing that the half-life for acetaminophen ranges from 1 to 4 hours. Kovach et al.

(1999) recommend that for persons with dementia who cannot report pain symptoms, "the use of a limited trial of analgesics in response to a broad array of physical and behavioral symptoms" may be a good method of determining whether or not the person is experiencing pain and may provide the most appropriate intervention for the patient (p. 417). Ferrell (1995) reports that acetaminophen is the most commonly prescribed analgesic for elderly nursing home patients, and supports its use as the preferred analgesic choice for patients without substantial inflammation because of its lower side-effect profile. In fact, in a study conducted by Chinball and colleagues (2005), where 3,000 mg of acetaminophen was administered in 3 daily 1,000 mg doses for 4 consecutive weeks, there were no adverse events related to the acetaminophen and all post-study liver function tests were normal. Likewise, in a sample of 519, only one person had an allergy to acetaminophen and one other had a drug interaction with acetaminophen (Buffum et al., 2004).

The American College of Rheumatology (2000), the European League Against Rheumatism (2003), and the British Medical Journal (2000) all agree that for persons with OA experiencing mild to moderate joint pain, the appropriate first line pharmacologic agent is acetaminophen (Tylenol). This is in agreement with the guidelines derived specifically for older adults by the American Geriatrics Society (2002) described above. It should be noted, however, that none of these guidelines gives specific recommendations for persons with dementia. However, the general scientific opinion is that dementia does not affect the experience of pain, just the memory of it. Therefore, it follows that these guidelines should be applicable and safe in older adults with dementia.

In summary, further investigation into pain management in older adults with dementia warrants attention due to the promising results found by previous researchers. Because the prevalence of musculoskeletal pain in older adults in general is large and there is no reason to believe that persons with dementia do not experience equivalent levels of pain as cognitively intact older adults, it is imperative that this pain be assessed and managed effectively. Several methods of assessing pain behaviors in cognitively impaired older adults have been shown to be reliable and valid. However, many need to be evaluated in terms of showing sensitivity to treatment effects. The creators of the Pain Assessment for the Dementing Elderly (PADE) state that a limitation of their validation of this tool was that it lacked an intervention phase; specifically, they state that it would be of interest to see if PADE scores were to decrease in response to analgesic administration (Villanueva et al., 2003).

The other area of considerable importance is the relationship between chronic pain and behavioral problems as well as limitations in functional performance in persons with dementia. It is these excess disabilities that place a significant amount of stress and burden on the caregiver. If treating the underlying chronic pain condition can have a positive effect on behavioral problems and functional limitations, this would be of clinical significance to the caregiver as well as lead to a better overall quality of life for the person with dementia. Clinicians have begun to recommend that behavioral problems in persons with dementia need to be considered in the multiple contexts from which they can develop, many of which are other identifiable problems, such as pain, and that treating these behavioral problems should always begin with correcting any underlying medical conditions and alleviating any discomfort (Kahn et al., 1998; Lantz, 2003).

Therefore, the proposed pilot study aims to evaluate the effects of an analgesic trial in reducing observable pain behaviors as well as reducing behavioral problems and functional limitations common in persons with dementia. In order to accurately assess and evaluate the effects of any intervention, it is imperative to know the patient's baseline level of behavior, compare any changes in behavior over time, initiate interventions, and then evaluate the effect of these interventions with the same assessment tools (Buffum et al., 2001).

Summary

A review of the literature exploring the assessment and treatment of chronic pain in persons with dementia provided support for the need for an analgesic trial to reduce pain behaviors in this population. Furthermore, this review highlighted several issues which were addressed in the present study, including the use of caregiver assessments of care recipient pain and the relationship between chronic untreated pain and excess disabilities. Based on the recommendations of the leading treatment guidelines and the paucity of studies investigating drug treatment for pain in older adults with chronic pain and dementia, acetaminophen was the appropriate treatment choice for this feasibility study. The literature review also supported investigating the effect of around-the-clock dosing of acetaminophen on the frequency and severity of excess disabilities in persons with dementia. Finally, the use of observational measures to assess change in pain behaviors after the implementation of a pain treatment intervention was strongly supported in the literature.

CHAPTER 3
METHODS

Study Design

This feasibility pilot study was conducted using an ABAB single-subject design. Through this design, the research participant served as his or her own control through the use of repeated observations which controls for inter-subject variability (Crosbie, 1995). This particular design was used in order to investigate the feasibility and effect of implementing a scheduled analgesic trial on participant pain behaviors and excess disabilities related to chronic pain, and also attempted to capture the significance of an individuals' change in behavior. The ABAB design was able to examine the effects of acetaminophen by alternating a baseline condition (phase A- no acetaminophen administered) with the intervention condition (phase B). These phases were then repeated to complete the four phase design. In this type of design, the effects of the intervention are evident if measures of participant pain behaviors and excess disabilities decrease during the first intervention phase, "revert to or approach original baseline levels of performance when treatment is withdrawn, and improve when treatment is reinstated in the second intervention phase" (Kazdin, 1982, p. 110). This longitudinal, feasibility design to study the effects of acetaminophen in persons with dementia is needed as there is a paucity of literature on the effectiveness of acetaminophen to alleviate pain in community-dwelling persons with dementia. Thus, the study was intended to provide important preliminary data about this important, but understudied phenomenon.

One benefit of SSD is that it allows for a relatively small N, generally at least three subjects are required, which is convenient when the target population is difficult to recruit for research studies (as was the case for community-dwelling persons with dementia and their caregivers) (Kazdin, 1982). SSD analysis has traditionally consisted of visual inspection of the graphic display of data, with occasional use of statistical tests to evaluate the reliability of findings, especially in cases with variable or trend-affected baselines (Greenwood & Matyas, 1990; Kazdin). This allows the researcher to view an individual's data points during the baseline observation phase and from the intervention phase on an ongoing basis. Then, judgment for when to switch phases, as well as about an intervention's effects, is made based on the overall pattern of the data (Hoerster, Hickey, & Bourgeois, 2001; Morgan & Morgan, 2001).

A drawback of SSD is that the number of measurement occasions needed is dependent upon how quickly baseline stability is established in order to begin the treatment phase and then how long it takes to observe a treatment effect. Thus, the length of a phase depends on the nature of the phenomenon being investigated. If it is relatively stable in nature and responds quickly to an intervention, the study phases can be relatively short. Likewise, if it is more labile in nature and slower to respond to an intervention, the phases will need to be longer to observe baseline stability and the intervention's effect. Since pain is generally somewhat variable in nature, and the effectiveness of acetaminophen on reducing chronic pain in persons with dementia is unknown, this study departed from the traditional methods for changing phases. Rather than observing for stability in pain behaviors in the initial baseline phase before introducing the intervention, the treatment was give after 8 days of baseline data

collection. This allowed for the collection of information on the intra-individual variability of pain behaviors in persons with dementia. Also, due to the unknown effect of acetaminophen or how long it may take to show any effect, the initial intervention phase was created to last the same number of sessions (8) as the baseline phase in order to give the design equivalence.

SSD has not been widely employed in nursing research, in part due to some of the criticisms about determining the effect of an intervention through visual inspection. Despite the reliable criteria for visual inspection (such as comparing the magnitude and rate of change to the variability of performance during a phase, the duration of the phase, and the consistency of the effect across phases or baselines), critiques of SSD persist (Kazdin, 1982). One criticism has been that visual inspection of data caters to interventions with strong effects (Greenwood & Matyas, 1990). If an intervention's effects are strong, there will be convincing graphical evidence that the intervention was responsible for the change in behavior, thus virtually eliminating any chance of a Type II error. However, when an intervention's effects are more subtle or more variable, there is a high risk for Type I error as the graphical analyses of this intervention's effect may find that the intervention failed to effect any change in behavior (Crosbie, 1995). This is, when statistical procedures may be employed in order to test the strength of the intervention's effects when they appear weak or non-existent based on graphical analyses.

For this proposed feasibility study, a SSD provided the needed combination of flexibility in sample size and measurement occasion requirements while paying rigorous attention to the nature of individual change. Because the effect of acetaminophen in

reducing pain and its related behaviors in community-dwelling persons with dementia is unknown, a SSD, with ongoing analysis of graphical data, allowed the researcher to observe effects immediately. While this design does not allow for comparisons across individuals and does not rely on complex statistics for analysis, it should be noted that the proposed study is a feasibility study, and this design allowed the researcher to carefully follow the trend of the data and adjust the study phases according to participant performance. This design allowed the researcher to examine daily change in behavior and to carefully format "the nature of change in the single case before seeking similarities and differences across cases" (Nesselroade, 1984, p. 275).

Sample

Five community dwelling older adults (over age 65) with dementia and their primary caregiver were recruited and enrolled to participate in this study in order to obtain a target sample of three pairs to complete the study. Two pairs (40%) were withdrawn by the Principal Investigator. Informed consent was obtained from the legally authorized representative of all participants with dementia and assent was obtained from all participants with dementia. The primary caregiver for each participant also signed an informed consent form to participate in daily sessions with the Principal Investigator over the course of a 4-6 week period, as well as to complete several daily measurement tools and administering multiple doses of acetaminophen on a daily basis according to study protocol. Each caregiver was also the health care surrogate and legally authorized representative of the participant with dementia. Each caregiver and their care recipient also resided together in the same dwelling.

Recruitment Procedures

Individuals with dementia and their primary caregivers were recruited from the West Central and North Central Florida community. Initial recruitment included working with local chapters of the Alzheimer's Association through which the PI gained access to present the study to members of Alzheimer's Caregiver support groups. Flyers were posted and announcements were placed in local church bulletins. The PI also gained permission to attend the University of Florida's neurology clinics and the Memory Disorders Clinic to identify possible participants. Also, local family practice and geriatric physicians were asked to advertise the study to potentially eligible participants.

Inclusion and Exclusion Criteria for Participants with Dementia

Inclusion criteria consist of: 1) previously established diagnosis of probable Alzheimer's Disease (AD) or other related dementia by a physician, 2) score of 23 or less on the Mini Mental State Exam (MMSE), 3) age 65 or over, 4) diagnosis of a painful musculoskeletal condition, such as osteoarthritis (OA), 5) able to swallow an oral pill (as assessed by the principal investigator), and 6) not currently taking prescribed analgesics on a regular basis. As advocated by previous researchers, persons receiving routine aspirin for cardiovascular prophylaxis (81 mg/day) were allowed participate in the study and continue this regimen (Chinball et al., 2005). Participants were excluded if they are unable to walk or have a hypersensitivity to acetaminophen that would prohibit them from taking this drug. Also, persons with major health problems, especially any kidney or liver disease, were excluded.

Inclusion and Exclusion Criteria for Caregivers

Caregivers recruited for this study were required to be the primary caregiver to the participant with dementia as well as be able to read and write the English language

fluently. To be considered the primary caregiver, this person must have provided direct care to the individual with dementia and have had daily contact with him/her so that they were able to observe the participant over the course of the day.

Participant Pair 1, Caregiver 1 (CG 1) and Participant 1 (P 1)

The first participant pair consisted of a 58 year-old daughter (CG 1) who was the primary caregiver for her 79 year-old mother (P 1). Both were Caucasian and educated at the high school level. The mother was widowed and the daughter was married. Both resided in the same house with the daughter's husband and her adult son. At the time of the study, the daughter had been the primary caregiver for her mother for approximately one year and was receiving respite care one afternoon each week.

Participant Pair 2, Caregiver 2 (CG 2) and Participant 2 (P 2)

The second participant pair consisted of a 75 year-old wife caring for her 83 year-old husband. Both were Caucasian with a technical or trade school education. They resided together in an independent dwelling with no other residents. At the time of the study, the wife had been functioning as a caregiver for approximately 2 years and her husband attended an adult day care group for approximately 5 hours a day on weekdays.

Participant Pair 3, Caregiver 3 (CG 3) and Participant 3 (P 3)

The third participant pair consisted of a 67 year-old daughter caring for her 93 year-old mother. Both were Caucasian. The mother had an 8th grade or less education and the daughter had attended some college. The mother was widowed and the daughter was divorced. They resided together in the daughter's home with no other residents. At the time of the study, the daughter was employed full-time as an administrative program assistant and had an independent aid supervise her mother during the day. She had been serving as her mother's caregiver for approximately 2 years.

Participant Pairs Withdrawn from the Study

As mentioned previously, two of the five pairs that were enrolled in this study were withdrawn before completion by the PI. One of these pairs, an African-American daughter caring for her mother, completed the first two study phases. However, during the initial treatment phase (described below) the caregiver was unable to administer the treatment drug according to protocol (i.e. the treatment was administered only one time each day instead of the minimum of two doses to satisfy the study protocol which aimed to provide continual pain relief). The second pair withdrawn consisted of a Caucasian wife caring for her Caucasian husband. This pair completed only the first 6 sessions of the study (the first phase, described below, was 8 total sessions). This pair was withdrawn after it became clear that the participant with dementia was no longer providing assent to participate in the study and was aggravated at being asked to perform the activity protocol by his caregiver.

Measures

Comprehensive Intake Assessment

Once the caregiver expressed willingness to participate in this study, the principal investigator arranged an initial meeting in the residence where the individual with dementia receives care to explain the study, obtain informed consent, and to screen participants for eligibility based on the inclusion and exclusion criteria. Caregivers provided their own consent for study participation and also provided proxy consent for the person with dementia, as each caregiver was also the health care surrogate and legally authorized representative for their care recipient with dementia. (Copies of the informed consent forms are provided in Appendices B and C). Assent from each individual with dementia was also obtained at each session. Each participant with dementia was given

the Mini Mental State Examination (MMSE) by a trained research assistant (Folstein, Folstein, & McHugh, 1975). A score of 23 or less was used as a cutoff to verify cognitive impairment in participants with a diagnosis of dementia. Caregivers' cognitive status was judged to be intact by the PI through conversation and training procedures during this initial session; caregivers were not asked to complete formal cognition tests.

Demographic information, including age, sex, gender, marital status, education level, and race was collected. Also a medication log sheet was used to compile care recipients' prescribed and over the counter medications. Both caregivers and individuals with dementia were also screened for depression with the 15 item form of the Geriatric Depression Scale (GDS) (Sheikh & Yesavage, 1986), or the Center for Epidemiological Studies Depression Scale (CES-D) if they were less than 65 years of age. The Dementia Rating Scale-2 (DRS-2) (Mattis, Jurica, & Leitten, 2001) was administered to individuals with dementia in order to gain more accurate baseline measures of cognition as well as to thoroughly describe sample characteristics.

Caregiver Ratings of Pain Behaviors and Excess Disabilities

The Pain Assessment for the Dementing Elderly (PADE) was used to assess pain behaviors and pain-related disability. This tool was originally designed to assess pain in older adults with dementia residing in long-term care facilities (Villanueva et al., 2003). This tool was divided into three parts (i.e. subscales) and contained 24 total questions. Responses were provided using either a Likert scale (scored 1-4, or 0 for a skipped or N/A answer) or multiple choice (scored 1-4) to elicit information about the effects of pain on physical, global assessment, and functional areas. Part I of this measure assessed physical manifestations of pain such as observable facial expressions, breathing patterns, and posture. Responses on Part I were scored so that higher scores were representative of

higher distress. Part II consisted of one question which allowed the caregiver to rate, on a Likert Scale (none to severe), their global assessment of the individual's level of pain at the time of observation. Part III assessed functional performance and allowed caregivers to rate the individual's performance of ADLs. Part III was scored so that higher scores represented less independence and higher difficulties with ADLs. (See Appendix D for a copy of the PADE tool). Because the directions for the PADE tool asked caregivers to base their responses to Parts I and II of this measure on a 5- to 10-minute observation of the subject, caregivers were asked to complete these sections after observing the participant with dementia perform a 10-minute activity protocol (described below).

This measure was chosen because it was designed for caregivers to use to rate global assessments of pain, pain behaviors (e.g. facial expressions, breathing, posture), and ability to perform activities of daily living. Another reason for including this measurement tool is that it has shown significant correlations with measures of agitation in the elders with dementia and has proven to be quick and easy for caregivers to use. PADE intraclass correlation coefficients (ICC) were generally high (interrater ICC= 0.54-0.95; stability ICC= 0.70-0.98; internal consistency (α) =0.24-0.88). The PADE was also significantly correlated with the Cohen-Mansfield Agitation Inventory (r= .30-.42). The PADE was also able to differentiate individuals who were judged to suffer from clinically problematic pain from those who were not.

The Revised Memory and Behavior Problems Checklist (RMBPC) was designed to allow caregivers to measure problems with memory, depression, and disruptive behaviors exhibited by the person with dementia (Teri et al., 1992), and it is the most commonly used tool to measure behavior problems in community-dwelling individuals with

dementia (Allen, Kwak, Lokken, & Haley, 2003). This measure consists of 24 items and asks the caregiver to report the frequency of the problem in question and their reaction to this problem (i.e., how much it bothered them) over the preceding week. For the purposes of the proposed study, this was modified slightly to have caregivers report the frequency of and their reaction to problem behaviors for each day of the study. (See Appendix D for a copuy of the RMBPC). The RMBPC has shown good overall reliability for patient behavior (α= 0.84) and caregiver reaction (α= 0.90). The measure also has been shown to be valid as the depression subsection was positively correlated with Hamilton Depression Rating Scale (r=.44) and the memory-related problems subsection was positively correlated with the MMSE (r=.48).

Caregivers also completed a third, brief, free-response questionnaire composed of the following two open-ended questions: 1) How typical was this day compared to most days? (i.e. where there any doctor's appointments, visitors, etc.) and 2) What behaviors did you notice that were most representative of pain in the participant today? (Please include anything that signaled pain to you, even if it was not part of the other two questionnaires). (See Appendix D for a copy of this questionnaire).

These measures were selected because they were designed for use by caregivers to rate specific behaviors related to the study's specific aims. Together, these measures also addressed each of the 6 main types of pain behaviors described in American Geriatrics Society's (2002) pain behavior framework. Daily administration of the PADE allowed for frequent assessment of participants' pain behaviors in order to examine daily variations of these behaviors (during the observation phases) and the effectiveness of acetaminophen in reducing these behaviors (during the treatment phases). Also, because

measures of ADLs were recorded in this tool, the effectiveness of acetaminophen in increasing participants' functional ability was also assessed. Daily assessments with the RMBPC allowed the researcher to evaluate daily variation in participants' mood and problem behaviors (in observation phases) as well as the efficacy that reducing pain has in secondarily improving mood and decreasing problem behaviors in persons with dementia (in treatment phases). See Table 3-1 for a summary of study constructs and measures. Also, by assessing the typicality of the day, any potential influences on participant behavior or caregiver burden, such as the increased stress of taking the participant to a doctor's appointment, were noted. Also, it was thought that asking caregivers what pain behaviors they are most noticing would allow the researcher to establish which behaviors are most useful in signaling pain to community-dwelling dementia care providers.

Trained Observer Ratings of Pain Behaviors

The trained observer (i.e., the Principle Investigator or a trained research assistant who was familiar with administering the study tools and who was physically present at the data collection session) also completed the PADE (Parts I and II) daily as well as the frequency portion of the RMPBC for the first and last day of the study. (In this study, the trained observers consisted of the PI and two trained research assistants; one a PhD candidate in nursing and the other a senior high school student in the International Baccalaureate program). Since both the trained observer and the caregiver based their measures on the PADE part I and II on the same 10-minute observation of the participant performing the activity protocol (described below), this provided a way to measure inter-rater reliability between the two groups for assessing pain behavior.

Table 3-1. Study Constructs and Measures

Constructs	Measure	Subject Burden
Pain		
-Caregiver and trained observer reports of pain	-Sum score of PADE Part 1: Physical (observable facial expression, breathing pattern, and posture); and Part 2: Global assessment of overall pain	-PADE total time to complete for Parts I-III is 5-10 minutes
-Behavioral observation of pain	-Total number of pain behaviors observed during an activity protocol	-20 minutes total for activity protocol, 10 minutes to set up and take down equipment and 10 minutes for videotaping
-Self-reported pain	-average score on the NRS	- 1 minute
Pain outcomes/ correlates		
-Functional performance	-Sum score of PADE Part 3: Functional (ADLs)	-PADE total time to complete for Parts I-III is 5-10 minutes
-Behavioral disruptions	-Total and subgroup scores on RMPBC for memory-related problems, depression, and disruptive behaviors	-RMPBC total time to complete is 10-15 minutes

PADE: Pain Assessment for the Dementing Elderly
ADLs: Activities of Daily Living, including dressing, feeding oneself, and transfers
RMPBC: Revised Memory and Problem Behavior Checklist
NRS: Numeric Rating Scale

As mentioned previously, participants also performed a videotaped activity-based protocol derived from Keefe and Block's (1982) work with chronic low back pain patients. Initial findings using the behavioral observation system showed a highly significant correlation between pain rating with total frequency of observed pain behaviors ($r = .71$, $p < .01$). This activity based protocol was previously revised to facilitate assessment of pain behaviors in persons with dementia by Ann L. Horgas, PhD, RN; RO1 #NR05069-01. Using this revised protocol, each participant was asked to perform 4 normal activities of daily living (sitting, standing, lying, and walking in place) as well as transferring to and from each of these activity states. Each activity was performed for a period of one minute, with activities being repeated to reach a behavioral

observation time total of 10 minutes. The order of these activities was randomized for each session and the activity protocol was videotaped. The trained observer coded each videotaped activity protocol for the specific pain behaviors described below. Since each participant must have a diagnosis of OA or other painful condition, activities of daily living are deemed to be sufficient stimulants of pain because they represent activities that people with chronic pain often have difficulty with, but that are not too difficult for participants to perform (Keefe et al., 1986). These activities are also ecologically valid as they represent normal and generalizable everyday activities for all older adults who are not so frail as to be confined to a bed or wheelchair. Furthermore, previous studies have shown that increases in observable pain behaviors during activities rather than at rest (Herr et al., 2006).

Participants were also asked at each session to self-report their pain level using the numeric rating scale (NRS), both before starting the activity-based protocol and after the protocol was completed. The NRS is the self-report tool of choice for this study because it has been considered conceptually easier to understand by the elderly. This may be because of the added number selections on this scale as compared to other pain rating scales (Herr & Mobily, 1993). The NRS was presented as a horizontal line with 0= no pain as the left anchor and 10= worst pain as the right anchor with equally spaced dashes for each number 1-9. Participants selected the number from 0 to 10 that most accurately identifies the pain in question. This measure has been shown to be both valid and reliable in older adults (Gagliese & Melzack, 2003). See Table 3-1 for a summary of study constructs and measures.

Treatment Protocol

For the purpose of this study, Tylenol Arthritis Pain Extended Relief was the analgesic of choice for use as the treatment drug. This form of acetaminophen was chosen for its more convenient 3 times per day dosing over the 4 times per day dosing of Tylenol Extra Strength and Regular Strength Tylenol. Tylenol Arthritis has the same safety and side effect profile as the other forms of Tylenol. The difference is that each 650 mg pill of acetaminophen has an immediate release outer layer and a delayed released inner core so each dose (2 pills) provides up to 8 hours of pain relief. Furthermore, "most of the acetaminophen dose is released from the tablet matrix within 5 hours, but peak acetaminophen serum concentrations may be delayed 8 hours or longer following ingestion" (BC Drug and Poison Information Center, 2005, p.1). Acetaminophen is thought to cause analgesia by inhibiting prostaglandin synthesis in the central nervous system (i.e. elevation of the pain threshold) and the therapeutic serum levels for analgesia are 5-20 mcg/mL (Health Digest, 2006; Physician's Desk Reference, 2006). The dose response curve specific for Tylenol Arthritis medication indicate that the peak plasma concentration level (near 9.5 mcg/mL) is reached between 1 and 2 hours after administration, and declines to nontherapeutic levels (less than 5 mcg/mL) 6 hours after administration (McNeil PPC, 2002).

The dosing schedule for the treatment drug was designed for each individual participant to follow a continuous dosing pattern during the participant's waking hours. This means that the caregiver was asked to give two 650 mg pills to the participant every eight hours while the participant was awake. The typical sleep and wake schedule of each participant was taken into account when devising a typical dosing schedule. For example, a possible dosing schedule could then be to take the first dose with the morning

meal (9-10am) and a second dose with the evening meal (5-6pm). Alternatively, if the participant is currently taken another medication every eight hours, the caregiver was asked to give the treatment drug along with the other medication(s) as long as there were no contraindications to doing so.

The Tylenol Arthritis medication was provided to the participants free of charge by the PI. A large enough bottle to contain the amount of pills needed for the entire study was supplied. Participants were allowed to retain any remaining pills at the end of the study. The dosing schedule was worked out in advance with each caregiver to fit the daily routine for the individual with dementia. Caregivers were also provided with a medication log highlighting this dosing schedule to serve as a reminder to administer the treatment drug. Based on the participants' daily routines, a 2 time/day dosing schedule (morning after waking and approximately one hour before bed) was established for participants 1 and 3. Since participant 2 was awake more hours of the day, a 3 time/day dosing schedule was established (morning, early afternoon, and late evening). However, it is important to note that although there were dosing differences, each of the participants received the maximum number of doses during waking hours in order to provide continual pain relief without disrupting sleep patterns.

Statistical Power

Because this study was a feasibility pilot study to test the effects of an acetaminophen trial, the power of this study was not computed. There have been few research studies specifically looking at the statistical power of acetaminophen in reducing pain in persons with dementia. Although Buffum, Sands, Miaskowski, Brod, and Washburn (2004), found that 650 mg of acetaminophen given four times per day was no more effective than prn acetaminophen in reducing discomfort in persons with dementia,

this study targeted nursing home residents with severe dementia. It is quite possible that the results may be different in community-dwelling persons with more moderate dementia. Likewise, in an informal study, Douzjian and colleagues (1998) found 650 mg doses of acetaminophen three times a day to be an effective pain reliever. This lends support that using an even stronger dosage (two 650 mg pills up to three times per day) would also be effective in reducing pain. Furthermore, Chinball and colleagues (2005) found moderate-to-strong effect sizes ($eta^2 = 0.14\text{-}0.29$) for acetaminophen in improving outcomes assessed by the Dementia Care Mapping tool in nursing home residents with moderate-to-severe dementia.

While acetaminophen is the first line recommended analgesic, it is not the most powerfully acting analgesic available. However, it is reasonable to assume that given its endorsement by leading geriatric treatment guidelines (American College of Rheumatology, 2000; American Geriatrics Society, 2002; British Medical Journal, 2000; European League Against Rheumatism, 2003), that it will produce at least a small effect. Also, the validity and reliabilities of the PADE, RMBPC, and the original activity protocol designed by Keefe and Block (1982) as well as the revised activity protocol (Horgas, 2001), support that these tools will useful in detecting changes in participant behavior.

Procedures

As shown in Table 3-2, this ABAB single-subject study design consisted of an initial baseline daily observational phase (A_1) lasting a minimum of eight sessions within a two-week period to observe behavior under conditions before treatment was implemented. As described above, this study departed from the traditional methods for

Table 3-2. Study Design

Variables	Session 1 (Baseline)	Baseline Session 2 3 4 5 6 7 8	Intervention Session 9 10 11 12 13 14 15 16	Baseline Session 17 18 19 20	Intervention Session 21 22 23 24
Intake Measures	X				
Outtake Measures					X
Caregiver Instruction	X (Tool Administration)	X (Medication Administration)			
Caregiver Rating					
-PADE	X	X X X X X X X	X X X X X X X X	X X X X	X X X X
-RMBPC	X	X X X X X X X	X X X X X X X X	X X X X	X X X X
Acetaminophen			X X X X X X X X		X X X X
Activity Protocol	X	X X X X X X X	X X X X X X X X	X X X X	X X X X

changing phases. While the target goal was to have daily sessions, due to the unpredictable nature of collecting repeated measurements in persons with dementia, it was thought that it might not be convenient or possible for the caregivers to meet with PI on subsequent days throughout the study period. For this reason, guidelines for a minimum number of sessions within a maximum time-period were established. Typically the initial baseline phase is continued until the participant's behavior appears to be stable "or until it is evident that the response does not improve over time" (Kazdin, 1982, p.111). Since pain is labile in nature, it was proposed that at least eight baseline sessions would be needed to observe each individual's typical pain behavior patterns. The baseline phases of this design were necessary to describe the current level of behavior as well as to predict what future behavior would have looked like without an intervention.

Once the typical pain behavior pattern was observed, the intervention phase (B_1) was initiated. In an effort to create equivalence between study phases, this phase was also eight sessions in length (within a two-week period). Similarly to the baseline phases, the intervention phases describe current behavior and predict future behavior if the intervention were to be continued. However, the intervention phases also test the predictions from the baseline phases. That is, the investigator can test whether behavior in the intervention phase actually departs from the predicted baseline level. The return to baseline phase (A_2) began with the withdrawal of the intervention in an attempt to show that the participant's behavior would return to baseline performance without the intervention. This phase was planned to last a minimum of four sessions (if behavior returned to baseline levels rapidly) to a maximum of eight sessions. The unique purpose of this second A phase was to test the prediction from the B_1 phase. If behavior returned

to A_1, levels then it would be clear that the predicted and obtained performance levels differ, suggesting that the intervention withdrawal altered behavior. Following the return to baseline phase, the intervention was reimplemented (phase B_2). This phase was also planned to last a minimum of four sessions to a maximum of eight sessions. If in this phase, behavior again improves, the overall pattern of results would strongly suggest that the intervention was responsible for the change in behavior.

During the study, the Principal Investigator or a trained research assistant conducted all activity protocols using a digital video camera to capture each session. An effort was be made to try to schedule all videotaped sessions at the same time each day in order to establish a routine that will cause less burden for the caregivers and to try to control for variability in pain experienced at different times of the day. Also, it should be noted that because the half-life of acetaminophen is 1 to 3 hours, the standard washout of 3.5 half-lives would occur within 10 hours (Buffum et al., 2004). Thus, there is no need for a washout period between phases B1 and A2. During any days were the caregivers were unable to meet with the research team, they were told they could complete the daily measurement tools for that day if they chose too. However, CG 1 completed all 24 sessions within 25 days, CG 2 completed the study within 24 days; and CG 3 completed the study within 26 days, so there were not many instances of gaps between visits by the research team.

Phase A_1, Session 1

Day 1 of the study consisted of participant and caregiver screening for enrollment. A trained research assistant administered the MMSE separately to the participants with dementia to confirm cognitive impairment. The participants were also given a comprehensive intake assessment in order to thoroughly describe and evaluate sample

characteristics. Consent was obtained from the caregivers, who were each, also the legally authorized representative of their care recipient and assent was obtained from the participants with dementia themselves. Caregivers were asked to provide a current list of all of the medications that the participant received, including any over the counter medications. A medication log for each phase of the study listing all of the participant's medications was created and given to the caregivers to use as a log to record daily administration of all medications. In an effort to increase the reliability of caregiver ratings, caregivers also received instruction and training in administering the PADE and the RMBPC. Sample videotapes were shown to the caregivers in an effort to increase their knowledge of pain behavior as well as their ability to identify excess disabilities. They were asked to administer these tools themselves in front of the principal investigator to ensure understanding of tool administration.

Caregivers received a packet of measurement tools for each phase of data collection. To facilitate data collection, the measurement tools were printed in 14-point font on white paper (to facilitate reading). In addition, the packet was organized and clearly labeled to delineate the correct measure for each session. Also, on this day, the initial videotaped activity protocol was completed. Finally, caregivers and the trained observer completed the PADE and RMBPC regarding participant behaviors, and the caregivers answered the questions regarding the typicality of the day as well as if they noticed any pain behaviors that they thought most indicated pain.

Phase A_1

Throughout this baseline observation phase, the PI or trained RA completed the activity protocol and the PADE, and the caregivers completed both the PADE and the RMBPC during the visit. Since an effort was made to time study sessions at

approximately the same time each day, caregivers were instructed to think back over the participant's behavior since the previous day's session (or for the previous 24 hours if sessions did not occur on subsequent days) and to accurately reflect this behavior on the measurement tools. Additionally, they were asked to evaluate if this was a typical or atypical day for the participant (i.e. were there visitors, were they ill, or did they visit the doctor?) and to describe what behaviors they most noticed as indicating pain. Caregivers also recorded administration of all medications on the log sheet provided.

Phase A_1-Final Session

For the final session in the observation phase (8th session), the PI instructed caregivers on how to appropriately administer the treatment drug, acetaminophen, and worked with the caregiver to make a convenient dosing schedule/plan. After setting up the schedule (e.g. 900 hours and 1700 hours or morning meal and evening meal) for each individual, the caregiver administered the first dose of acetaminophen at the next scheduled time, after the activity protocol for that day was completed. Caregivers then received a packet for the second study phase including the daily questionnaires and medication log sheets with an additional space for recording when the treatment drug was given. Again, the PI and the caregivers completed the daily behavioral assessment tools and the caregivers provided information regarding the typicality of the day as well as the pain behaviors they noticed.

Phase B_1 (Eight Sessions)

During the second study phase, (the first intervention phase), caregivers continued to administer both the PADE and the RMBPC during the daily visits and recorded if the day was a typical day for the participant as well as the pain behaviors they noticed in the participant. In addition, the caregivers gave the treatment drug, as per the previously

established schedule, and recorded the time of administration on the log sheets provided. Participants continued to perform the videotaped activity protocol and the PI or trained RA also completed the PADE.

Phase A_2- Return to Baseline (Range of 4-8 Sessions)

Caregivers continued to log all medication administration during this week but were instructed to discontinue giving the treatment drug. Caregivers were, however, instructed that they could administer rescue doses of pain medication as needed by the participant, but to make sure to log these doses on the medication log sheet. Data collection proceeded as before in Phase A_1.

Phase B_2- Reimplementation of Intervention (Range of 4-8 Sessions)

This phase proceeded exactly as the original intervention phase. Caregivers were instructed to resume giving the intervention drug at the previously scheduled dosing times, logging all medications given. Participants continued to perform the activity protocol videotaped by the PI or trained RA, and the both the PI or trained RA and the caregivers completed the measurement tools as previously described. Caregivers also provided information regarding the typicality of the day as well as the most frequent behaviors that they saw in the participants that represented pain. On the last day of this phase, qualitative information regarding the caregivers' perceptions and satisfaction of the pain treatment was gathered. The PI or the trained RA also administered the Geriatric Depression Scale and the Dementia Rating Scale to the participant with dementia and the depression scale to the caregiver as part of an outtake assessment to evaluate changes in depression and cognitive performance over the course of the study.

Data Coding

Each videotaped activity protocol was coded using Noldus The Observer software the day it was recorded. This enabled the PI (who was the primary coder) to evaluate participant performance on an immediate basis in order to accurately assess behavior and the need for changes in study phases. Since all videotaping was done using digital video cameras, the media files were transferred to the computer using Dazzle Video Pro software and were then opened in The Observer's viewing window. Each media file was saved on an external hard drive as a backup. A coding program was created in the Observer that allowed independent coders to code the media files for specific pain behaviors. The independent variables entered in this program were participant ID number, study phase, and session number of the phase. Two categories of behaviors were used in this program, state behaviors and event behaviors. State behaviors are behaviors that occur for an unspecified amount of time, this requires that a behavior remain 'active' for the entire duration that this behavior is observed. Event behaviors are behaviors that are observed, but the duration of the behavior is not coded. The Observer requires that all state behaviors in a behavioral class be mutually exclusive; that is, no two behaviors in the same behavioral class can be active at the same time.

A second independent trained coder (who was an honor's student in the undergraduate nursing program) coded 25% of all videotapes to ensure inter-rater reliability and primary coder accuracy. This second coder was blind to the phase of the study in which videotaped sessions had occurred. Coder reliability was measured with the Kappa statistic (K) which not only takes into account the frequency of agreements between coders, but also accounts for the number of agreements one would expect as a function of chance (Blomqvist & Hallberg, 1999). A Kappa of 0.80 was established as

the criterion for coder training. Coders trained on practice tapes until their intra-rater reliabilities were greater than a kappa of 0.80 and were considered trained when their inter-rater reliabilities were greater than a kappa of 0.80 on practice tapes when compared with the master coder. For this study, the two raters reached an average inter-rater agreement of kappa =0.84, or 84% on the practice tapes (K range= 0.72-0.96), which meets the established criterion for training (Elder, 1999; Keefe, Bradley, & Crisson, 1990; Keefe & Hill, 1985). Reliability estimates for the actual study tapes were also good at kappa =0.80 (K range=0.62-0.98). This was considered to indicative of good reliability as there were 9 behaviors, 5 activities, and an actual total of 17 codes that coders used for the same observation, and other researchers have proposed that reliability coefficients between .60-.80 indicate good to very good reliability (Blomqvist & Hallberg; Gibson & Helme, 2000). Training strategies to increase inter-rater reliability included informal discussions about coding behaviors, independent study of the training manual (containing definitions and instructions for coding the variables of interest), and practice coding sessions with the 'master coder' and all research assistants

The two independent coders coded participants' activity protocols by recording the specified pain behaviors of interest that have been adapted and modified by Horgas (2001) from definitions of behavioral coding categories originally employed by Keefe et al. (1986). See Table 3-3 for the specific behaviors of interest for this study.

Data Analysis Procedures and Variables of Interest

RMBPC

The RMBPC yields both a global summary score and subscores for participants' behavioral disturbance and caregivers' reactivity. Also, frequency and reaction scores for

the three specific subscales (Memory-Related Problems, Depression, and Disruptive Behaviors) were computed.

PADE

The PADE is divided into three parts with Part I representing the physical domain, Part II representing a global assessment domain, and Part III representing the functional domain. Since questions are answered on either a Likert scale (range 1-4, or 0 for skipped answer or N/A) or with multiple choice (1, 2, 3, or 4), sum scores for each of the three parts were computed along with a total measure score.

Activity Protocol

Coding of the activity protocol yielded information about the duration and frequency of state behaviors (i.e. guarding, bracing, & rigidity) and the frequency of event behaviors (i.e. sighing/nonverbals, rubbing, stopping, grimacing, shifting, and vocalizations). Therefore, the mean time spent in a state behavior and the mean frequencies of all behaviors were calculated by Noldus the Observer software and used in the analyses.

Additional Caregiver Questionnaire

Caregiver responses as to the pain behaviors that they most frequently noticed to be indicative of pain in the participant were tabulated with frequency counts of specific behaviors listed by the caregiver.

Overview of the Analysis of Single-Subject Design Data

The overall objective of data analysis in any research study is to examine whether a truthful change has been demonstrated and whether or not this change is attributable to the intervention. In single-subject research, this is accomplished by examining the effects of an intervention at different points over time (Kazdin, 1982). In ABAB design, the

Table 3-3. Behavioral Definitions

ACTIVITY (STATE)	**MOVEMENT (STATE)**	**BRACING (STATE)**	**COMPLETING ACTIVITY (STATE)**	**PAIN BEHAVIORS (EVENTS)**
Sit = begin coding when Ss' buttocks rest on chair	**Rigidity** = Stiffness of the lower body (from back down to feet) – exhibited by Ss maintaining the affected lower body part in a stiff and abnormal position *during standing, sitting, or lying down*	**Bracing** = holding onto *someone or something* for support (e.g., walker, bed, cane) - participant-initiated behavior. *If tester initiated* behavior, code as bracing if there is evidence that the participant needed support (e.g., was unstable or falling.). Can occur during sit, stand, walk and transfer, but not during lying down.	**Stopping** = interrupting/stopping the activity state *during any activity state except transfer*; stopping the activity they are supposed to be doing (Ex: while walking – stopping to stand still or sit down; while standing, stopping to sit down; quitting the activity state)	**Rubbing** = touching, rubbing, or holding the affected lower body part (e.g., lower back/waist to feet) (palms down) *Code 1 completed circular or forward/backward movement as one rub.*
Stand = begin coding when Ss is in an upright position with one or both feet on the floor	**Guarding** = abnormally slow, stiff, interrupted, or rigid movement – *during transferring or walking*			**Shifting** = shifting of weight. This includes changing position or shifting weight (side to side shifts) of the trunk, hips, or lower extremities while doing an activity. [Excludes front to back sway.] *Can occur during any activity*; shifting during walking would reflect purposeful shifts in the lower back or trunk.

Table 3-3. Continued

ACTIVITY (STATE)	MOVEMENT (STATE)	BRACING (STATE)	COMPLETING ACTIVITY (STATE)	PAIN BEHAVIORS (EVENTS)
Walk = begin coding when Ss is in an upright position, and begins moving feet in marching/walking pattern **Lie** = begin coding when Ss' head and back touch the bed (horizontal position) **Transfer** = begins when the 1-minute activity state ends (When the timer rings to end the 1-minute activity, code this as beginning the transfer activity). End transfer when the next 1-minute activity begins				**Grimacing** = Obvious change in facial expression, indicated by frown (tightened lips, corners of mouth pulled back or down) and eye change (narrowed eyes and furrowed brow). **Sighing/Non-verbal Vocalization** = an obvious exaggerated exhalation of breath, usually accompanied by shoulders rising and falling or change in lip/mouth position **OR** any *spontaneous* non-verbal sound such as moaning, groaning, gasping, grunting. **Verbal Complaint** = *spontaneous expression* of pain or discomfort in affected body area (e.g., trunk, back, and lower extremities). [Verbal responses to questions or statements made in the context of questioning do not apply.]

effects of an intervention are replicated so a judgment as to the intervention's effectiveness is made on the overall pattern of the data. If participant behavior changes each time the intervention is applied and again when it is withdrawn, the effect of the intervention is apparent. These judgments are made based on the visual representation of the data. Visual inspection refers to "reaching a judgment about the reliability or consistency of intervention effects by visually examining the graphed data" (Kazdin, p. 232). As part of the design requirements, participant data are graphed continuously over the course of the study. These graphed data points represent the study behavior(s) of interest. There are several characteristics of the data that are examined in visual analysis of data. These characteristics are either related to the magnitude of change across phases (mean and level) or the rate of change (trend and latency). In addition, overlap of data points between phases and well as stability within a phase are also of interest (Kazdin).

A change in mean refers to a shift in the average rate of performance between phases. For this study, higher means of pain behaviors and excess disabilities were expected during the baseline phases and lower means were expected during the intervention phases. A change in level refers to the shift or discontinuity of behavior between the end of one phase and the beginning of the next phase. Since the trend or the slope of the data shows whether behavior systematically increases or decreases over time, a change in trend may be revealed when the intervention is applied or withdrawn. In the present study, decreases in level were expected when shifting from a baseline phase to an intervention phase, and increases in level were expected when shifting from an intervention phase to a baseline phase. Likewise, the trend (slope) was expected to be in the positive (increasing) direction during baseline phases and in the negative (decreasing)

direction during intervention phases. The latency of change refers to the period between the onset or termination of one phase and subsequent changes in behavior and is assessed by examining level and trend changes together. Therefore, the latency of change reveals how long after an intervention is applied it takes to change behavior. The closer this change takes place to the change in experimental condition, the more clear the effect of the intervention. In summary, "visual inspection is conducted by judging the extent to which changes in these characteristics are evident across phases and whether the changes are consistent with the requirements of the (study) design" (Kazdin, 1982, p. 237). Kazdin also points out that there are also specific background characteristics to examine in relation to the visual analysis of data. These characteristics speak to the reliability of an effect and are measured through examining the: variability of performance within a particular phase (stability), the duration of the phase, and the consistency of the effect across phases or baselines (overlap). (See the Appendix A for a detailed explanation for performing these graphical analyses).

One potential drawback to visual analysis is that only interventions that produce a large effect will be considered to have produced a change. In the case of an intervention that produces more modest effects, statistical evaluation may be warranted. While statistical evaluation is not the norm in single-subject research, there are several circumstances in which it can reveal significant intervention effects that may have been missed in visual analysis. Specifically, the statistical evaluation of single-subject data to supplement visual analysis is appropriate when there are unstable baselines, new areas of research are being investigated (intervention effects may be weak), there is increased intrasubject variability (where there is little control over the environment and potential

influences), or when even small changes in behavior may be important and meaningful (Kazdin, 1982). Appropriate statistical tests include conventional *t* and *F* tests (when there is no serial dependency between data points) and time-series analysis.

Statistical Analysis of Each Aim

Aim 1: To investigate the effects of the scheduled administration of acetaminophen (1.3 grams three times per day) on self-reported pain intensity and the number of observable pain behaviors exhibited by persons with dementia.

Hypothesis: Regular administration of acetaminophen will decrease the total number of observable pain behaviors (as rated by the caregiver and trained observers) exhibited by the participant, but will have no effect on self-reported pain intensities.

The variables of interest for these analyses included caregivers' and the PI's or trained RA's daily responses on the PADE part I and the total frequency and duration of individual pain behaviors as coded with the Observer from the videotaped activity protocol. These totals were graphed against the day of measurement. As described above, the standard in analyzing SSD data consists of visually inspecting dependent measures (i.e. total number of pain behaviors) during independent variable conditions (acetaminophen trial phase) relative to baseline measures (Morgan & Morgan, 2001). The data analysis and graphical interpretation occurred in an ongoing manner such that data were analyzed and graphed as soon as they were collected. At the conclusion of the study, the graph for each participant was interpreted to look for an overall pattern in pain behaviors during baseline phases before treatment and any change in the frequency or duration of behaviors after initiation of pain treatment. Specifically, changes in mean, level, trend, latency, overlap, and stability were examined. If warranted, statistical evaluation using *t* and *F* tests to "compare whether differences in means are statistically

reliable between, or among, the different phases" (Kazdin, 1982, p. 245) or time-series analysis to "examine whether there is a statistically significant change in level and trend from one phase to the next" (Kazdin, p. 248) were planned.

Aim 2: To investigate the effects of the scheduled administration of acetaminophen on the frequency and severity of excess disabilities of pain in persons with dementia.

Hypothesis: Among persons with dementia, the frequency and severity of excess disabilities of pain, such as depression, memory problems, behavioral disruptions, and impaired functional performance will decrease from baseline after implementing regular administration of acetaminophen.

The variables of interest are the frequency ratings for each of the three subgroups (memory-related problems, depression, and disruption) on the RMPBC and for the measure as a whole which were calculated for each participant daily. Also of interest for this aim are caregiver's responses on the PADE part III. Again, this data was graphed and analyzed as described for Aim 1.

Aim 3: To determine the reliability of informal caregiver ratings of the frequency of pain behaviors exhibited by persons with dementia.

Hypothesis: After an initial training session, informal caregivers will display moderate to good reliability with a trained observer in ratings of the frequency of pain behaviors.

The variables of interest were the caregivers' ratings on the PADE part I and the trained observer's ratings on the PADE part I. To evaluate the reliability of informal caregivers' ratings of pain behaviors, the caregiver's ratings were compared to those of

the trained observer's for each study session and the inter-rater reliability was calculated using Pearson's correlation coefficient.

Aim 4: To investigate the most frequently displayed behavior(s) indicative of pain that is/are displayed most frequently by persons with dementia.

Hypothesis: Based on findings from similar studies, the most frequently displayed behaviors indicative of pain are expected to be guarding, rubbing, shifting, and bracing (Horgas & Elliott, 2005; Keefe & Block, 1982).

The variables of interest are caregiver ratings on the PADE part I, the total number of individual pain behaviors as coded with the Observer from the videotaped activity protocol, and caregiver responses as to which behaviors they most noticed as being indicative of pain in the participant. The most frequently rated and coded behaviors were then extrapolated and this list of behaviors serves as the behaviors employed most by persons with dementia to relay pain.

CHAPTER 4
RESULTS

The results of the present study are presented below. First, all descriptive statistics are presented; specifically, scores on the initial cognition and depression measures for each participant are compared to their scores on these measures from the final day of the study. Initial and final caregiver depression scores are also presented. Next, the results for each of the 4 specific aims are presented. Of note, for aims 1 and 2, graphical representations of the variables of interest are presented individually for each participant. Each graph was then analyzed by looking at changes in the mean between phases, the latency of change between phases (which consisted of examining level and trend changes), the overlap of data points between phases, and finally, the stability of data within phases.

Descriptives

Initial Intake Measures

The intake Mini Mental State Exam (MMSE) score for Participant (P) 1 was 10, indicating moderate (near severe) cognitive impairment while the initial Dementia Rating Scale-2 (DRS-2) total score (31) indicated severe cognitive impairment. The intake depression measure indicated no depression (Geriatric Depression Scale score = 0). Initial depression scores for caregiver (CG) 1 indicated mild depression, (Center for Epidemiological Studies Depression Scale score of 19).

The intake MMSE score for P 2 was 20, indicating moderate cognitive impairment, while the initial DRS-2 total score (111) indicated severe impairment. The intake

depression measure indicated no depression (GDS = 1). Initial depression scores for CG 2 indicated no depression (GDS = 2) as well.

The intake MMSE score for P 3 was 5 indicating severe cognitive impairment and the initial DRS-2 total score (65) indicated severe impairment as well. The intake depression measure indicated no depression (GDS = 1) and initial depression scores for CG 3 indicated no depression (GDS = 2). Demographic data along with these scores are presented in Tables 4-1 & 4-2, comparing those pairs who completed the study to the two pairs that were withdrawn from the study.

Final Outtake Measures

During the last study session, final outtake measures were taken from both the participant and the caregiver. This was done specifically to see if there had been any change in cognition (for the participants) or depression (for both participants and caregivers) during the course of the study. Scores for these outtake measures are presented in Tables 4-1 & 4-2. As can be seen outtake DRS-2 total scores were exactly the same for Participants 1 & 2 as their intake scores. Interestingly, while there was some variation in subscale scores between intake and outtake measures, the total score remained the same. For P 3, the DRS-2 total score improved from 65 to 71, however, this increase in total score did not change her severely impaired classification on this measure.

Depression scores also did not show much change from intake assessment to outtake assessment. Participant 1 remained at 0 both occasions, and while Participants 2 and 3 showed declines on the GDS (1 to 0 for P 2, and 3 to 1 for P 3), although neither participant was initially classified as depressed. The same was true for Caregivers 2 and 3 (CG 2 decreased from GDS 2 to 1, CG 3 remained at GDS 2) who were not initially

Table 4-1. Descriptive Characteristics for Participants

ID	Age	Sex	Race[a]	Education[b]	Marital Status[c]	MMSE	Initial DRS-2 Score	Final DRS-2 Score	Initial Depression Score (GDS)	Final Depression Score (GDS)
Participants Included										
P1	79	F	0	3	2	10	31	31	0	0
P2	83	M	0	4	1	20	111	111	1	0
P3	93	F	0	1	2	5	65	71	3	1
Participants Withdrawn										
4	67	F	1	5	1	1	4		0	
5	78	M	0	3	1	18	99		1	

[a]0= Caucasian, 1= Black
[b]1= 8th grade or less, 2= 9-11th grades, 3= High School, 4= Technical or Trade School, 5= Some College
[c]0= Never been married, 1= Married, 2= Widowed, 3= Separated, 4= Divorced

Table 4-2. Descriptive Characteristics for Caregivers

ID	Age	Sex	Race[a]	Education[b]	Marital Status[c]	Relation to Participant	Initial Depression Score	Final Depression Score
Caregivers Included								
CG 1	58	F	0	3	1	Daughter	19 (CES-D)	22 (CES-D)
CG 2	75	F	0	4	1	Wife	2 (GDS)	1 (GDS)
CG 3	67	F	0	5	4	Daughter	2 (GDS)	2 (GDS)
Caregivers Withdrawn								
4	37	F	1	5	0	Daughter	12 (CES-D)	
5	77	F	0	3	1	Wife	5 (GDS)	

[a]0= Caucasian, 1= Black
[b]1= 8th grade or less, 2= 9-11th grades, 3= High School, 4= Technical or Trade School, 5= Some College
[c]0= Never been married, 1= Married, 2= Widowed, 3= Separated, 4= Divorced

classified as depressed. However, Caregiver 1, the only person in the study to initially have a score in the depressed category (on the CES-D) increased from an initial score of 19 to an outtake score of 22

Effect of Acetaminophen on Self-Reported Pain Intensity and Observable Pain Behaviors

The primary specific aim of this study was to assess the effect of scheduled doses of acetaminophen on self-reported pain intensity and the number of observable pain behaviors. Participants were asked to self-report their pain intensity using the numeric rating scale (NRS) both immediately preceding and following the activity protocol. Over the course of the study (24 sessions for 48 total occasions for self-report), P 1 self-reported no pain on all occasions. P 2 used the NRS on four occasions (with this being on both occasions at 2 sessions during the final treatment phase) to self-report mild pain intensity (scores of 1s and 2s on the NRS). P 3 used the NRS on six occasions (twice for both occasions at a session and twice preceding the activity protocol only) to self-report pain intensity. On five occasions, during both the baseline and treatment phases, this pain was mild (1s and 2s on the NRS) and on one occasion during the initial baseline phase, this pain was moderate (6 on the NRS).

The effect of acetaminophen on observable pain behaviors was evaluated by comparing pain behaviors exhibited by participants' during baseline performance of an activity protocol with their performance of the same protocol while receiving scheduled doses of acetaminophen. Several methods were used to observe for changes in performance. First, the total number and total duration of the previously defined target pain behaviors (see Table 3-3) were coded for using Noldus The Observer software. Changes in performance were also assessed with Part I of the PADE measure which was

completed daily by both the CG and the trained observer (TO) (i.e. either the Principle Investigator or trained research assistant who was physically present at the data collection session). In total, there were 4 measures employed to assess the effect of acetaminophen on observed pain behaviors exhibited by persons with dementia. The results for each of these measures are represented graphically for each participant. As part of the analyses of graphed data, changes in mean, the latency of change (i.e. comparing level changes between the end of one phase and the beginning of the next phase and the change in trend or slope between phases), overlap of data between phases, and the stability of data within a phase are presented. Complete descriptions of these components of graphical analysis are presented in Chapter 3. (See Appendix A for examples of how the mean, level, trend, latency, overlap, and stability were calculated).

Total Number of Pain Behaviors

Participant 1

Figure 4-1 displays P 1's frequency of pain behavior for each session during baseline and intervention conditions. **Mean:** During the initial baseline condition (A1), the mean frequency of pain behavior exhibited during the activity protocol was 32.1 behaviors per session. This mean frequency decreased to 18.6 after the introduction (B1) of the intervention (acetaminophen). Upon the return to baseline condition (A2), the mean frequency of behavior increased to 27.5 and then decreased to 17.5 when the intervention was reintroduced (B2).

Changes in both level and trend are analyzed together to examine the latency of change between phases. **Latency:** There was an 11 point decrease in level between phases A1 and B1, however, the trend in phase A1 was initially in the unintended direction (slope= -1.44) and flattened (slope= -0.04) in phase B1. Between phases B1

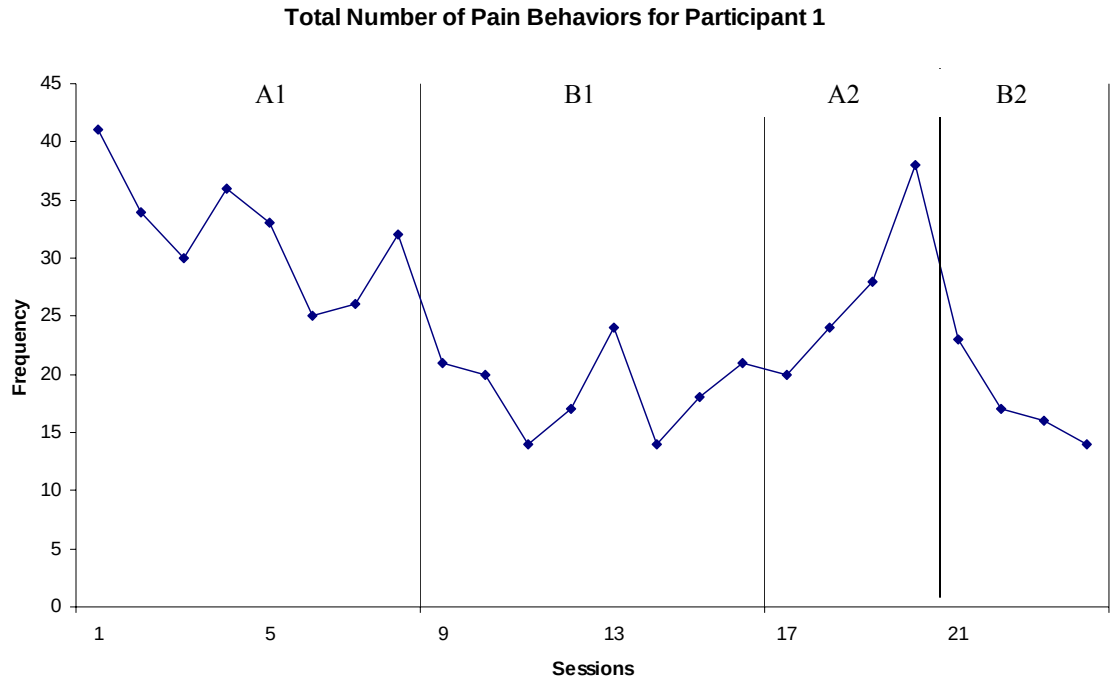


Figure 4-1. Total number of pain behaviors for P 1 across sessions from the coded activity protocols.

and A2, there was a small level change in the unintended direction (1 point decrease) but the there was a large change in trend in the intended direction (slope= -0.04 to 5.8). Finally, between phases A2 and B2, there was a 15 point decrease in level and a large change in trend in the intended direction (slope= 5.8 to -2.8). **Overlap:** There was nooverlap in data points between phases A1 and B1, while 2 points overlapped between phases B1 and A2, and 1 point overlapped between phases A2 and B2. **Stability:** There was 100% stability in the data points in phases A1, A2, and B2, while phase B1 had 62.5% stability in data points.

The changes in mean frequencies for each individual pain behavior by phase for Participant 1 are presented in Figure 4-2. Only behaviors which occurred greater than 25 times during the course of the study are included in these analyses. As can be seen, for

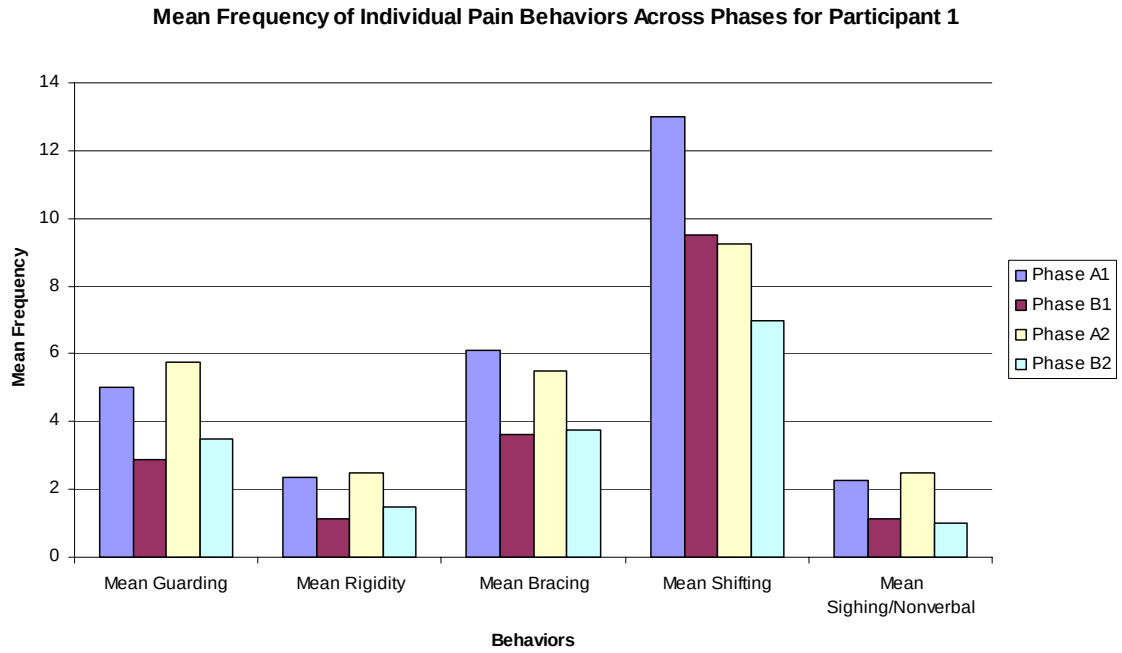


Figure 4-2. Mean frequencies for individual behaviors across phases for P 1.

each behavior except shifting, the mean frequencies are higher in the two baseline phases and are lower during the treatment phases.

Participant 2

Figure 4-3 displays P 2's frequency of pain behavior for each session during baseline and intervention conditions. **Mean:** The mean frequency of pain behavior in theinitial baseline phase (A1) was 33 behaviors per session, which decreased to 22.5 during the first intervention phase (B1). The mean frequency of behavior increased during the return to baseline phase (A2) to 31.3 and decreased to 20.1 when the intervention was re-introduced (B2). **Latency:** There was a 9 point decrease in level from the last session in phase A1 to the first session in phase B1, and a change in trend from a slope of 1.0 in the intended direction in phase A1 to nearly no trend (slope = 0.02) in phase B1. Although a large change in level between phases B1 and A2 (14 point increase) was observed, the

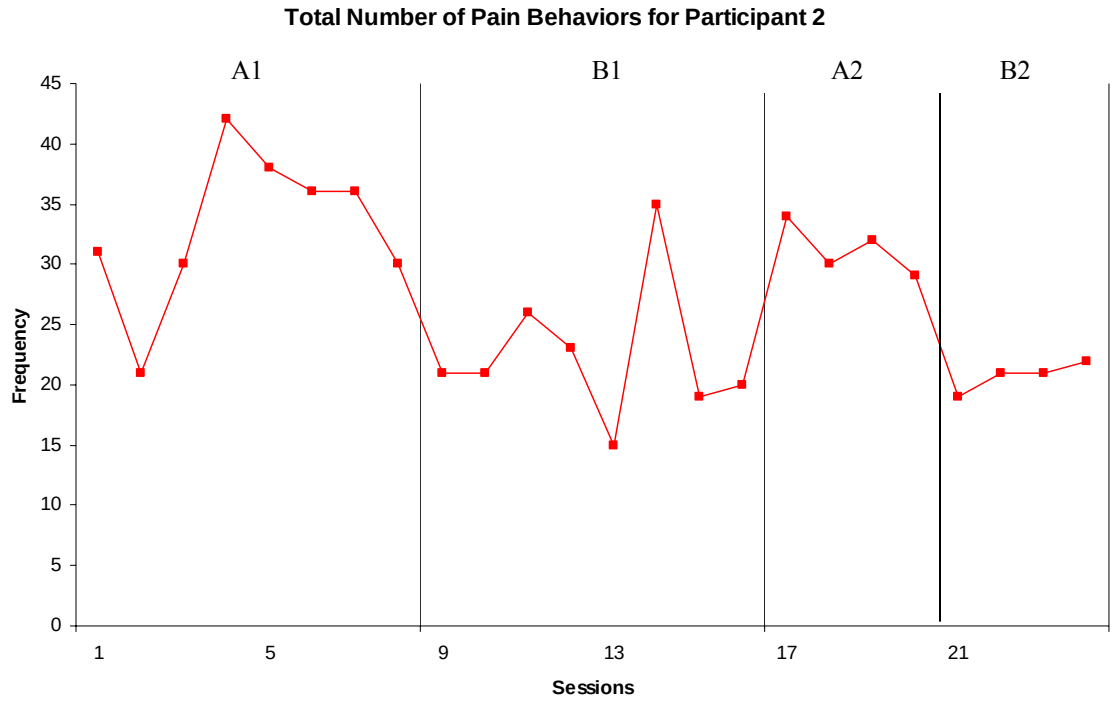


Figure 4-3. Total number of pain behaviors for P 2 across sessions from the coded activity protocols.

change in trend was in the unintended direction (slope= 0.02 to -1.5). Between phases A2 and B2 there was a 10 point decrease, accompanied by a change in trend in the unintended direction (slope= 0.9). **Overlap:** There was a 1 point overlap between phases A1 and B1 and also between phases B1 and A2. There was no overlap of data points between phases A2 and B2. **Stability:** There was 100% stability in data for phases A2 and B2, 62.5% for A1, and 75% for phase B1.

The changes in mean frequencies for individual pain behaviors by phase for P 2 are presented in Figure 4-4. Behaviors which occurred greater than 25 times during the course of the study are included in these analyses. As for P 1, for each behavior except shifting, the mean frequencies of each behavior are higher in the two baseline phases and are lower during both the treatment phases.

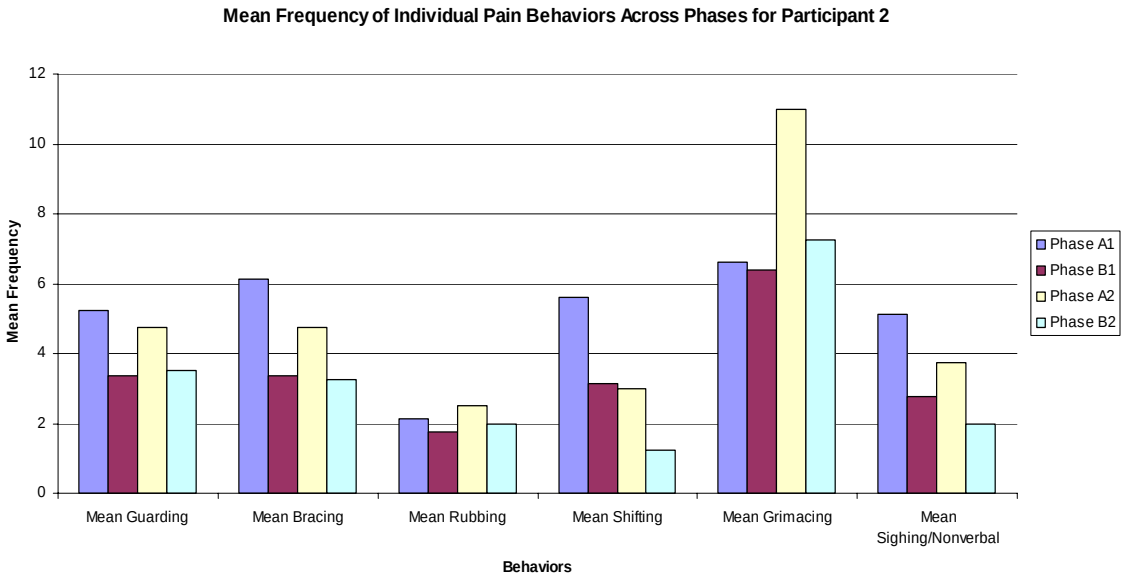


Figure 4-4. Mean frequencies for individual behaviors across phases for P 2.

Participant 3

Figure 4-5 displays P 3's frequency of pain behavior for each session during baseline and intervention conditions. **Mean:** The mean frequencies of pain behavior for P 3 were higher across all phases than for either Participant 1 or 2. The change in mean frequencies was as follows: 57.8 behaviors per session for phase A1, 30 for phase B1, 53.3 for phase A2, and 29.8 for phase B2. **Latency:** There was a 35 point decrease in level between the end of phase A1 and the beginning of phase B1, however, the change in trend went from a slope= 3.5 in the intended direction to a still accelerating slope of 1.2 in phase B1. Between phases B1 and A2, there was a 9 point increase in level, however, there was relatively little change in trend (slope= 1.2 to 0.9). There was a 28 point decrease in level between phases A2 and B2, however, the trend continued to accelerate in the unintended direction (slope= 2.1). **Overlap:** There was also no overlap of data points between any of the phases. **Stability:** The data were 100% stable in phases A2 and B2, 87.5% stable in phase A1, but had 25% stability in phase B1.

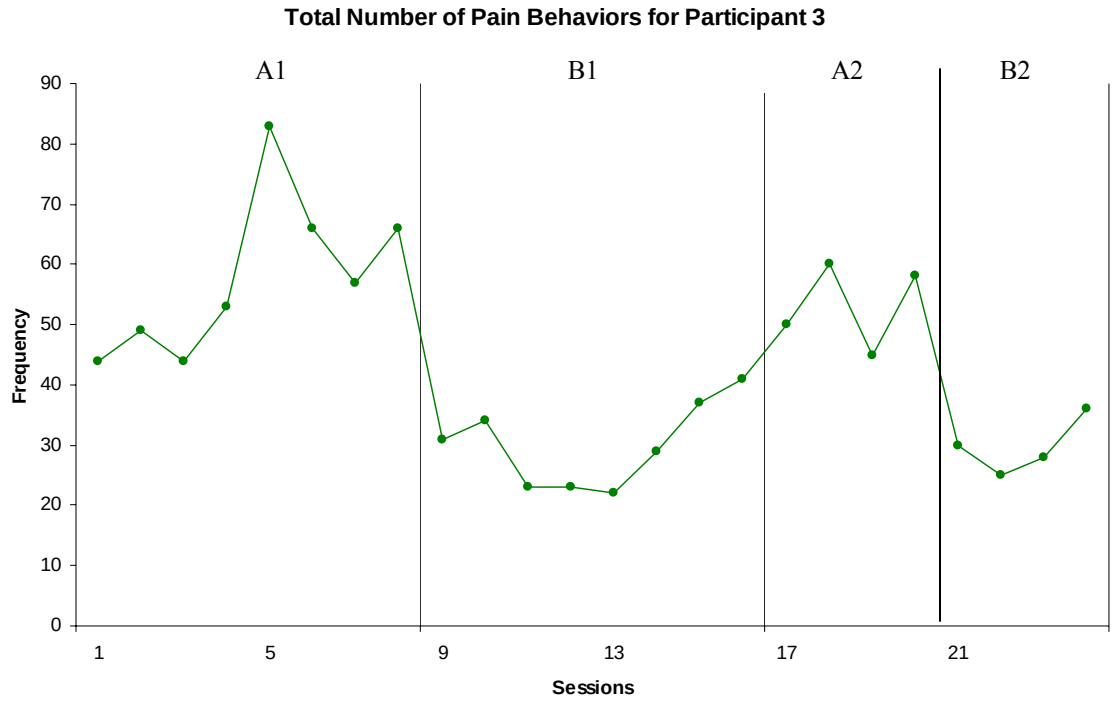


Figure 4-5. Total number of pain behaviors for P 3 across sessions from the coded activity protocols.

Changes in mean frequencies for each individual pain behavior by phase for Participant 3 are presented in Figure 4-6. Behaviors occurring greater than 25 times during the course of the study are included in these analyses. There is a clearly observed pattern of increased mean frequency during baseline phases and decreased mean frequency for intervention phases for guarding, rigidity, stopping, shifting, and sighing/nonverbal behaviors. The pattern is less clear for bracing and verbal complaints, but there is an initial decrease in these behaviors after the initial baseline phase.

Total Duration of Pain Behaviors

The following section presents study results regarding the effect of acetaminophen on the duration of pain behaviors. As mentioned previously, only certain

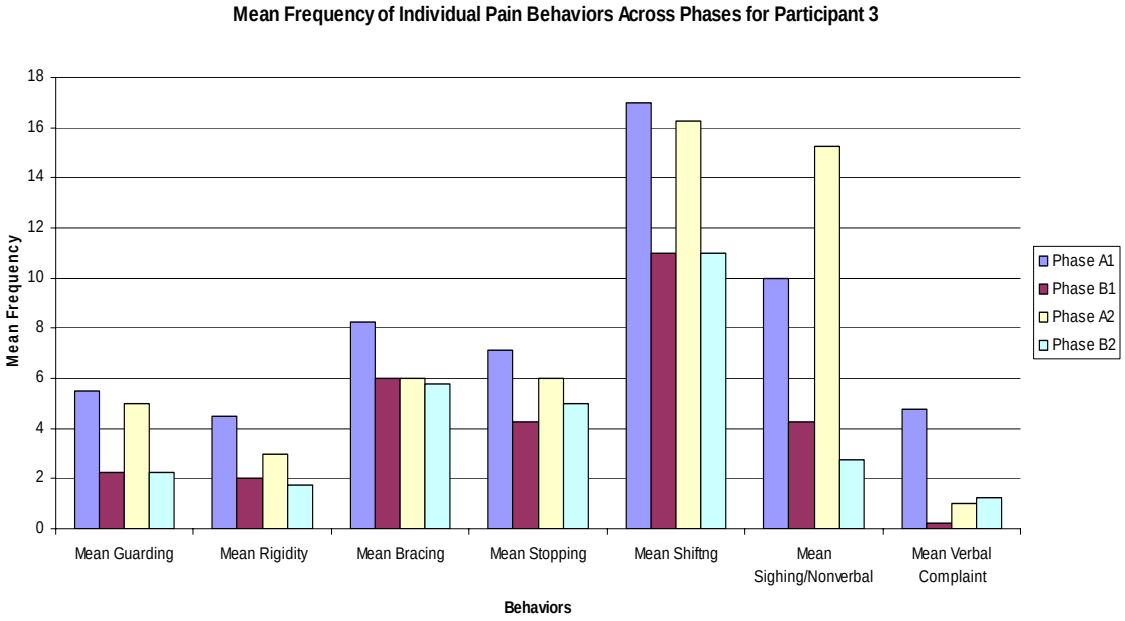


Figure 4-6. Mean frequencies for individual behaviors across phases for P 3.

behaviors were coded both for their frequency and their duration. These behaviors included: guarding, bracing, rigidity, and stopping.

Participant 1

Figure 4-7 displays P 1's total duration of the pain behaviors (e.g. guarding, rigidity, bracing, and stopping) in seconds for each session across all 4 phases. **Mean:** The mean durations for phases were as follows: 325.6 seconds per session for A1, 120.7 seconds for B1, 278 seconds for A2, and 155.4 for B2. **Latency:** In evaluating the latency of change between phases A1 and B1 there was a change in level of a 285.5 second decrease, and although the trend in phase A1 was in the unintended direction (slope= -4) there was a pronounced flattening of the trend in phase B1 (slope= -0.2). Between phases B1 and A2 there was a decrease of 56.3 seconds in level and a marked change in trend from a slope=-0.2 to a slope = 93.0. Finally, between phases A2 and B2 there was a 204.6 second decrease in level as well as a trend lessening to a slope= 12.4.

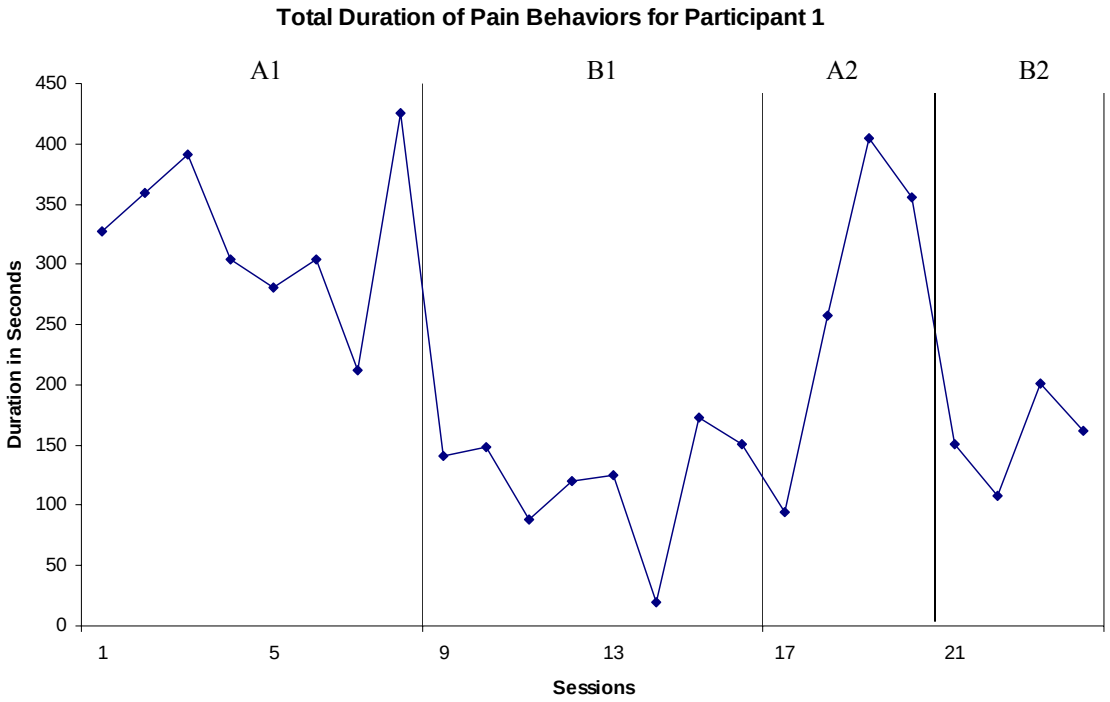


Figure 4-7. Total duration of pain behaviors for P 1 across sessions from the coded activity protocols.

Overlap: There was no overlap between phases A1 and B1, and only 1 point of overlap between phases B1 and A2, and A2 and B2. **Stability:** The data were relatively unstable, finding 62.5% stability in phase A1, 50% stability in phases A2 and B2, and only 25% stability in phase B1.

The change in mean duration for each behavior is shown in Table 4-3. The expected pattern of longer durations during the baseline phases and shorter durations during the intervention phases was seen for each behavior; although stopping was an infrequent behavior, occurring less than 5 seconds in each of the latter three phases.

Participant 2

Figure 4-8 displays P 2's total duration of the pain behaviors in seconds for each session across all four phases. **Mean:** The mean duration of pain behaviors was as

Table 4-3. Mean Duration (in Seconds) of Individual Pain Behaviors across Phases and Participants

Participant	Behavior	Phase A1	Phase B1	Phase A2	Phase B2
1	Guarding	151.2	59.3	121.5	59.7
	Rigidity	129.0	48.3	110.8	81.1
	Bracing	34.4	11.9	41.9	12.3
	Stopping*	10.9	1.2	3.8	2.4
2	Guarding	95.0	55.6	101.2	71.3
	Rigidity*	98.0	32.1	47.2	30.6
	Bracing	11.5	6.7	10.8	7.1
	Stopping*	0.8	3.3	5.3	3.3
3	Guarding	200.4	43.9	137.3	74.8
	Rigidity	225.2	112.9	128.2	80.4
	Bracing	304.8	257.0	263.7	222.8
	Stopping	43.4	12.4	16.6	13.4

* Infrequent behaviors (<25 total occurrences)

follows: 205.3 seconds per session during phase A1, 97.7 seconds during phase B1, 164.6 seconds during phase A2, and 112.2 seconds during phase B2. **Latency: B**etween phases A1 and B1 there was a marked decrease in level (159.5 seconds), however, the trend in the initial baseline phase was strong in the unintended direction (slope= -8.3) which flattened in phase B1 (slope= -0.8). Between phases B1 and A2, there was an increase in level of 138.7 seconds and an increase in trend (slope= 18.9) in the intended direction. Between phases A2 and B2, there was a decrease in level (188.2 seconds), however, the change in trend continued to increase to slope= 25.7. **Overlap:** There was a lot of overlap between data in this participant, 4 points between phases A1 and B1, 3 points between phases B1 and A2, and 2 points between phases A2 and B2. **Stability:** There was also little stability of the data in all phases (37.5% in A1, 12.5% in B1, 0% in A2, and 50% in B2).

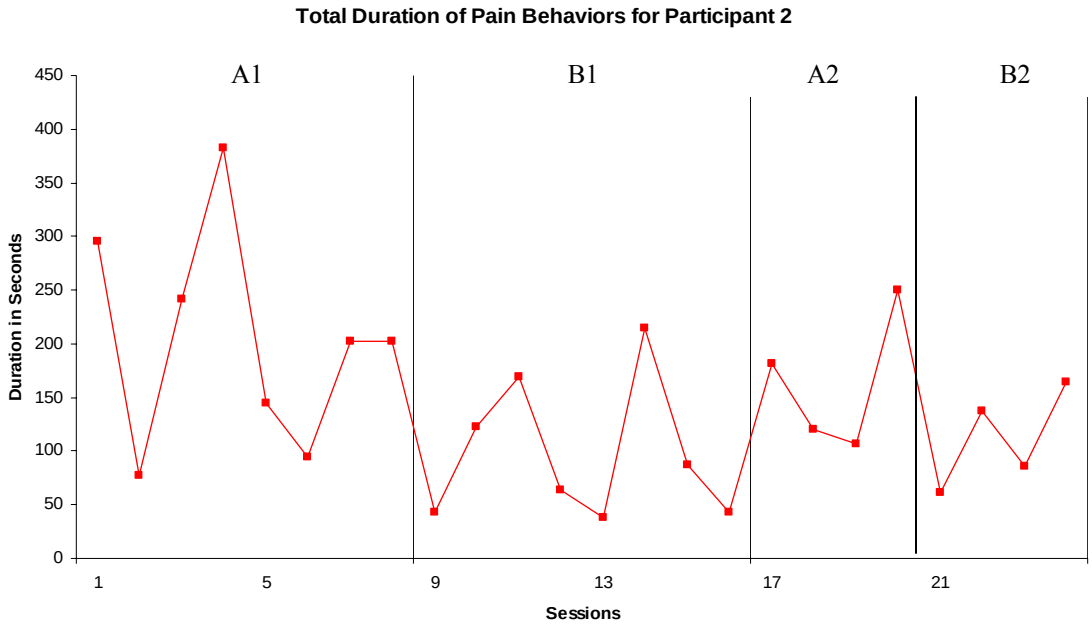


Figure 4-8. Total duration of pain behaviors for P 2 across sessions from the coded activity protocols.

The change in mean duration for each behavior is shown in Table 4-3. The expected pattern of longer durations during the baseline phases and shorter durations during the intervention phases was seen for each behavior, although rigidity and stopping were infrequent behaviors, with stopping occurring 5 seconds or less in each phase.

Participant 3

Figure 4-9 displays P 3's total duration of the pain behaviors in seconds for each session across all four phases. **Mean:** The mean total duration of pain behaviors was higher for P 3 than for the other two participants. The change in mean for phases was as follows: 773.8 seconds per session for phase A1, 426.2 seconds for phase B1, 545.9 seconds for phase A2, and 391.5 seconds for phase B2. **Latency:** Between phases A1 and B1, there was a 209.8 second decrease level and a trend change from a slope of 16.0

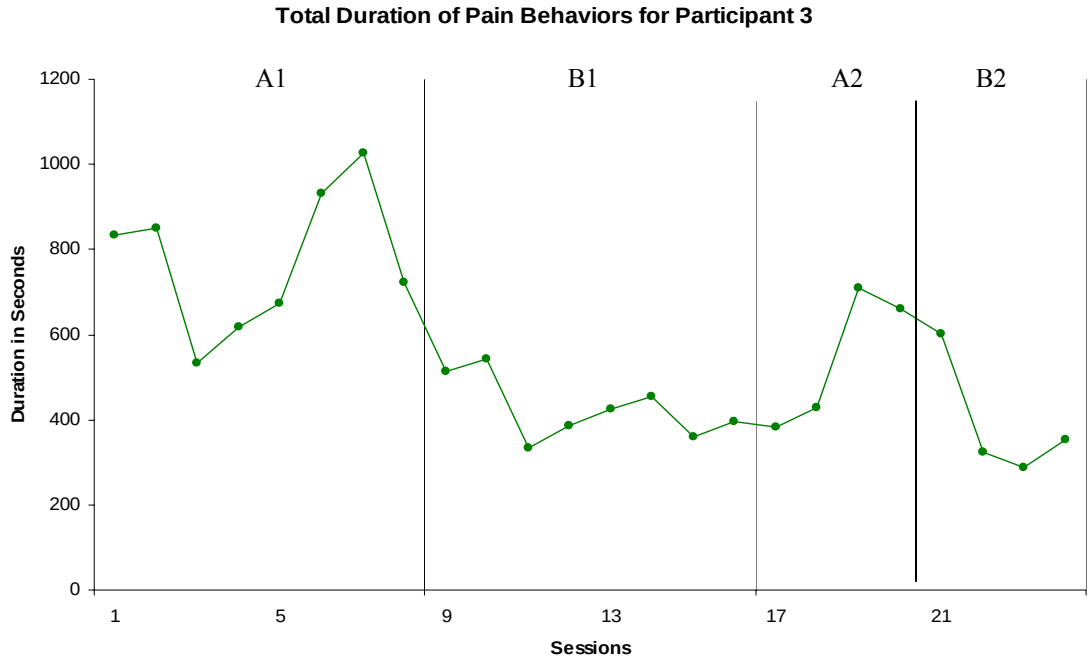


Figure 4-9. Total duration of pain behaviors for P 3 across sessions from the coded activity protocols.

in the intended direction to a slope of -16.0 in the intended direction for the intervention phase. This same effect followed for the latency of change between phases B1 and A2, although the change in level was a decrease of 12.3 seconds. The change in trend was strong with the slope increasing to 111.65 for phase A2. Between phases A2 and B2 there was a 60.6 second decrease for level change, and a change in trend to slope of -78.1. **Overlap:** There was one point of overlap between phases A1 and B1 and also between A2 and B2. There were 2 points of overlap between phases B1 and A2. **Stability:** Overall, the stability of phases varied, with 75% stability in phases B1 and A2, 50% in phase A1, but no stability (0%) in phase B2.

The change in mean duration for each behavior is shown in Table 4-3. Again, the expected pattern of longer durations during the baseline phases and shorter durations during the intervention phases was seen for all behaviors.

Caregiver and PI Pain Ratings on the PADE

Participants' pain behaviors were also assessed with Part I of the PADE. Both the CGs and the TOs completed this measure daily after having observed the participant perform the activity protocol. Scores on this measure could range from a minimum total score of 10, to a maximum score of 52, with higher scores representing more pain behaviors.

Participant 1

Total PADE Part I scores for P 1, rated both by the TO and CG, are presented together in Figure 4-10. As can be seen, the total scores of pain behaviors appears to be on a continuous decline over the course of the study. This is seen in both the CG's and the TO's ratings. **Mean:** The change in mean for the CG's ratings over the phases was as follows: 22.25 for phase A1, 17.63 for phase B1, 15.75 for phase A2, and 16.5 for phase B2. Trained observer change in means over phases followed the expected rise and fall pattern with a mean of 25.5 behaviors for phase A1, 20.63 for phase B1, 21.75 for phase A2, and 17.25 for phase B2. **Latency:** The latency of change pattern for CG's was as follows: 4 point level decrease and change of slope from -0.55 in the unintended direction to -0.44 between phases A1 and B1; one point level increase and change of slope in the unintended direction to -1.3 between phases B1 and A2; and a 10 point level increase and continued decline in slope to -3.0 between phases A2 and B2. The latency of change pattern for the TO's ratings consisted of a one point level increase and negligible change in slope from -0.5 to -0.56 between phases A1 and B1; a 4 point level increase with decelerating slope to -0.7 between phases B1 and A2; and a one point level increase and change in slope to -1.5 between phases A2 and B2. **Overlap:** There was the same

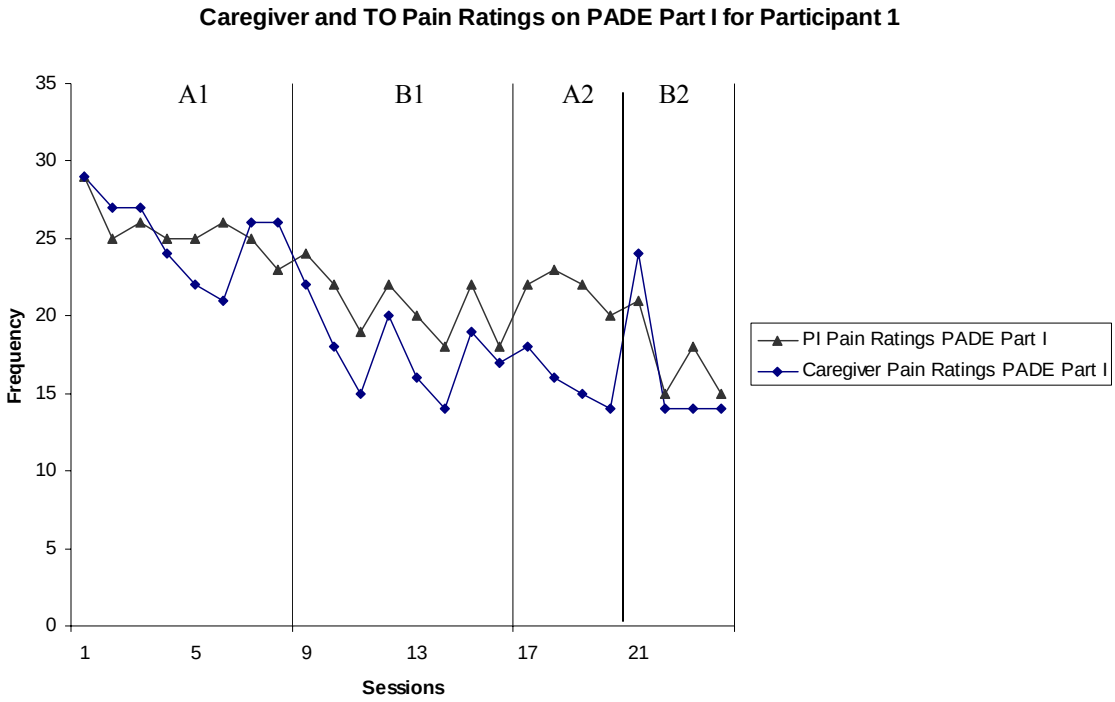


Figure 4-10. Caregiver and TO PADE Part I pain ratings for P 1 across sessions.

amount of overlap between phases for both the CG's and TO's ratings (1 between phases A1 and B1, 4 between phases B1 and A2, and 2 between phases A2 and B2). **Stability:** The TO's ratings were more stable over the course of the study (100% in phases A1, B1, and A2, and 75% in phase B2) than the CG's (100% in baseline phases, and 62.5% in phase B1, and 50% in phase B2).

Participant 2

Both the CG and TO's total PADE Part I scores for P 2 are displayed in Figure 4-11. The CG's ratings on this measure were mostly stagnant over the course of the study, while the TO's ratings reflected more day-to-day variability. **Mean:** Changes in the mean of the PADE part I scores over phases as rated by the CG was: 20.25 for phase A1, 20 for phases B1 and A2, and 19.75 for phase B2. Trained observer changes in the mean ratings on this measure were as follows: 21.75 for phase A1, 20.13 for phase B1, 22.25

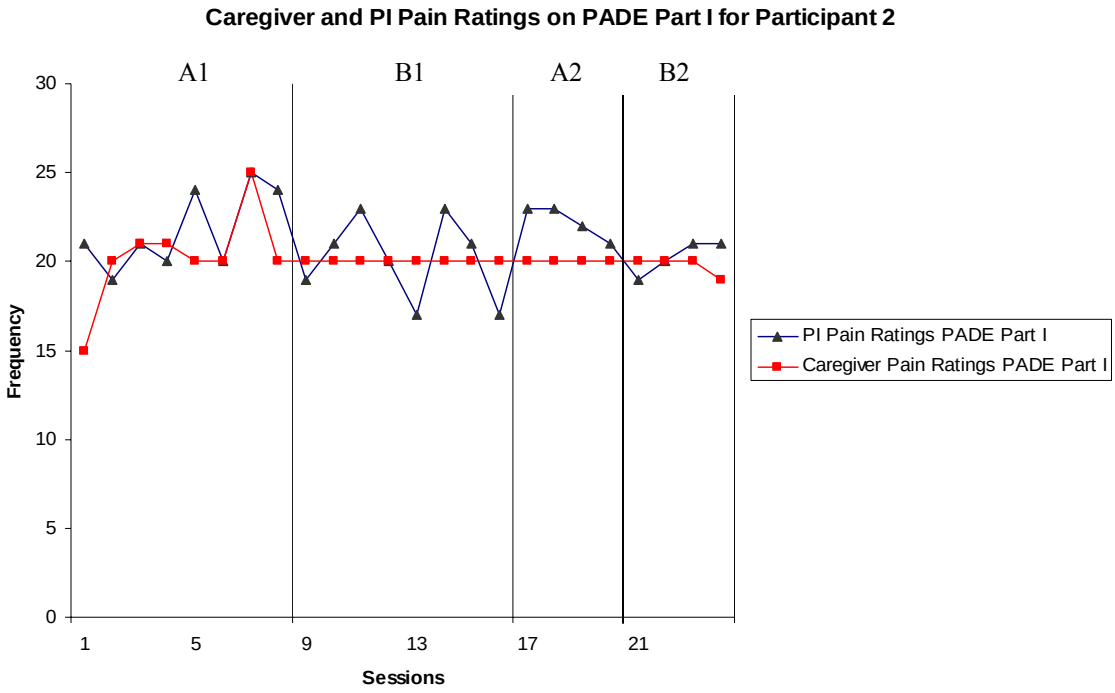


Figure 4-11. Caregiver and TO PADE Part I pain ratings for P 2 across sessions.

for phase A2, and 20.25 for phase B2. **Latency:** There was an initial change in trend between phases A1 and B1 (slope= 0.67 flattening to 0), with no change in level. Because the CG rated the same number of behaviors throughout sessions B1, A2, and most of B2 there was no change in either level or trend between phases B1 and A2. There was no level change between phases A2 and B2, but there was a slight change in trend to a slope=-0.3. The latency of change for the TO's ratings was slightly more in the expected direction. There was an initial change in trend from slope= 0.62 to -0.2 with a 5 point level decrease between phases A1 and B1. There was a 6 point level increase between phases B1 and A2, however, the slope continued to decline to -0.7. Finally, there was 2 point decrease in level between phases A2 and B2, although the slope changed in the unintended direction, accelerating to 0.7.

Overlap: There was much overlap for both the CG and the trained observer's ratings. For the CG, 5 points overlapped between phases A1 and B1, all points between phases B1 and A2, and 3 points between phases A2 and B2 overlapped. For the TO, 6 points between phases A1 and B1, all points between phases B1 and A2, and 2 points between phases A2 and B2 overlapped. **Stability:** Because of the consistency of the CG's ratings, there was 100% stability throughout the study. While more variable, the trained observer's ratings were also 100% stable throughout the study.

Participant 3

Both the CG and TO's total PADE Part I scores for P 3 are displayed in Figure 4-l2. This figure shows that the CG's ratings of pain on this measure start out high and then decline over the course of the study, with a slight increase at the end. The TO's ratings follow the expected pattern of increasing during baseline phases and decreasing with treatment. **Mean:** Changes in the overall mean PADE part I scores for the CG were as follows: 20.5 in phase A1, to 20.1 in phase B1, to 18.5 in phase A2, to 19.25 in phase B2. Mean changes as rated by the TO were: 22.88 in phase A1, decreasing to 19.75 in phase B1, increasing to 23.25 in phase A2, and decreasing again to 19.25 in phase B2. **Latency:** Change in latency for the CG's ratings was reflected by a 2 point level decrease and trend change from slope= 1.1 to -0.18 between phases A1 and B1; a 1 point level increase with a further deceleration of the slope to -0.6 between phases B1 and A2; and a 3 point level increase and slowing of the slope to -0.3 between phases A2 and B2. Changes in latency for the TO ratings were all in the intended direction (3 point level decrease and change of slope from 0.65 to -0.29 between phases A1 and B1; 3 point level increase and increasing slope to 0.1 between phases B1 and A2; 2 point level decrease and a deceleration of the slope to -0.1 between phases A2 and B2).

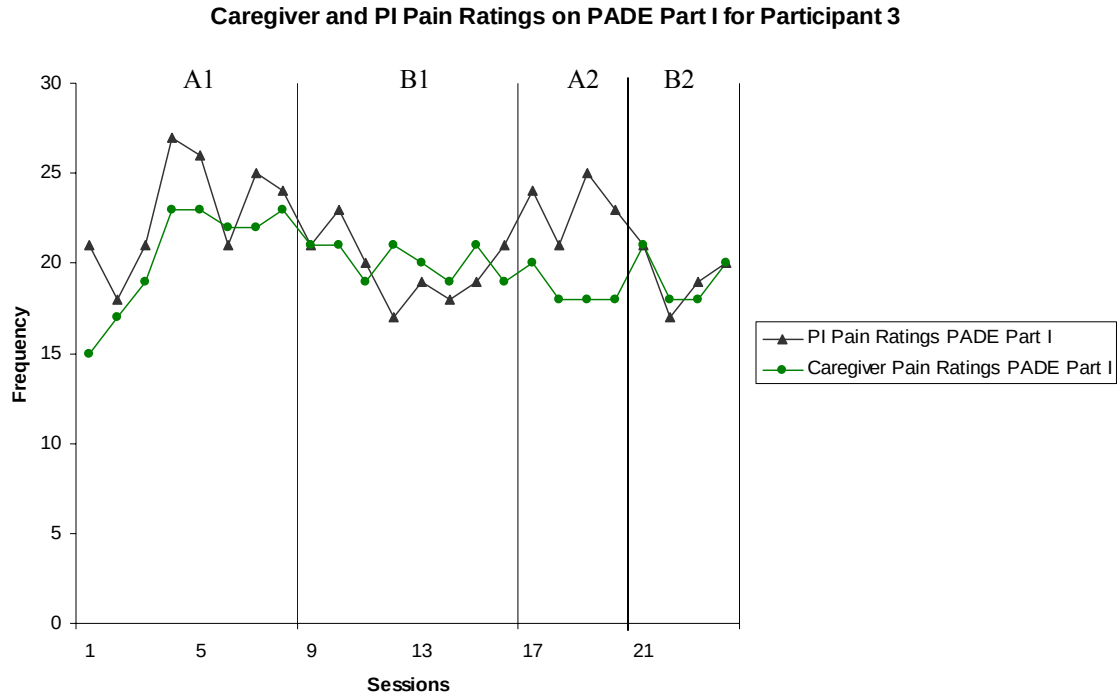


Figure 4-12. Caregiver and TO PADE Part I pain ratings for P 3 across sessions.

Overlap: There was also much overlap between data points in phases for this participant in both the CG's and the TO's ratings. For both, three points overlapped between phases A1 and B1, 1 point for the CG and 2 points for the trained observer overlapped between phases B1 and A2, while all points for the CG and 1 point for the TO overlapped between phases A2 and B2. **Stability:** Pain behaviors as rated by the CG were 100% stable throughout the study. Data were 100% stable in phases B1, A2, and B2 and 87.5% stable in phase A1 for the trained observer's ratings.

Effect of Acetaminophen on Excess Disabilities

The second specific aim of this study was to assess the effect of scheduled doses of acetaminophen on excess disabilities of chronic pain. This was done by comparing the frequency of excess disabilities displayed by participants' during baseline phases with the frequency displayed during treatment phases. Changes in frequency of excess disabilities

were assessed with the CG's ratings on the RMBPC (total measure score) as well as Part III of the PADE measure. Both of these measures were completed daily by the caregiver. In total, two measures were employed to assess the effect of acetaminophen on excess disabilities of chronic pain exhibited in persons with dementia. The results for these measures are presented graphically for each participant. Subscale scores on the RMBPC for memory, depression, and disruption are shown on the graphs as well for a more in-depth look at where change occurred for each participant. As above, changes in mean, latency (level and trend), overlap, and stability are examined. (See Appendix A for a complete description of calculating the mean, level, trend, latency, overlap, and stability).

Total RMBPC Score

The RMBPC measured excess disabilities related to problems with memory, depression, and disruption. The caregivers were asked to rate the frequency of 24 individual behaviors that were part of one of the three subscale domains. Scores ranged from 0 to 4 for each item, for possible total scores ranging from 0 to 96, with higher scores representing higher frequencies of excess disabilities.

Participant 1

The frequency of excess disabilities over the course of the study, as rated by the CG, for P 1 are displayed in Figure 4-13. Though showing some day-to-day variability, the trend in frequency of excess disabilities was a continual decline over the course of the study. **Mean:** The change in mean for phases shows this gradual decline as the mean frequency of excess disabilities in phase A1 was 32.75 compared to 27.13 for phase B1, 25.75 for phase A2, and 20.5 for phase B2. **Latency:** In terms of the latency of change for P 1, there was a large level change between each phase (7 point decrease between A1 and B1, 22 point increase between B1 and A2, and a 12 point decrease between A2 and

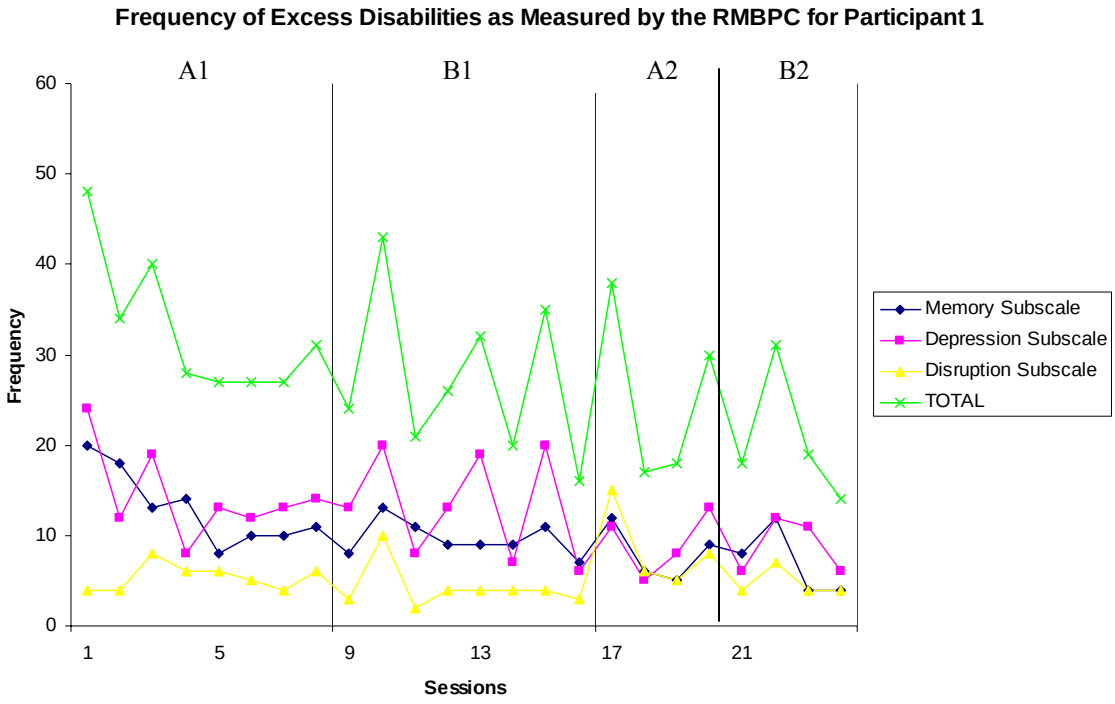


Figure 4-13. Frequency of excess disabilities across sessions for P 1, as rated by the CG, on the RMBPC.

B2), however, there was a decelerating trend in each phase (slopes= -.23 for phase A1, -1.11 for phase B1, -2.3 for phase A2, and -2.4 for phase B2) which is in the unintended direction for baseline phases. **Overlap:** There also considerable overlap between data points in study phases: 3 between phases A1 and B1, all 4 points overlapped between phases B1 and A2, and 3 of 4 points overlapped between phases A2 and B2. **Stability:** The data for the participant were not very stable; while there was 62.5% stability in phase A1, and 50% stability in phase B2, there was only 12.5% stability in phase B1 and 0% stability in phase A2.

By looking at Figure 4-13, it is also apparent that the excess disabilities for P 1 were more frequently on the depression and memory subscales. There was a gradual decline over the course of the study in the mean frequency of each phase for these

subscales (means on the depression subscale: 14.38 for A1, 13.25 for B1, 9.25 for A2, and 8.75 for B2; means on the memory subscale: 13 for A1, 9.63 for B1, 8 for A2, and 7 for B2). Problems in the disruption subscale were less frequently reported, but did follow the expected pattern. Mean frequencies for disruption were: 5.38 for phase A1, 4.25 for phase B1, 8.5 for phase A2, and 4.75 for phase B2.

Participant 2

The frequencies of excess disabilities over the course of the study, as rated by the CG, for P 2 are displayed in Figure 4-14. The frequency of excess disabilities starts high and gradually declines through the first treatment phase, where it becomes relatively stable for the remainder of the study. **Mean:** The mean frequencies of excess disabilities for each phase were as follows: 36.38 for phase A1, 29.38 for phase B1, 28.5 for phase A2, and 29.0 for phase B2. **Latency:** There were only small level changes between phases (2 point decrease between phases A1 and B1, 3 point increase between phases B1 and A2, and a one point decrease between phases A2 and B2) and the trend did not change greatly throughout the study, with a decelerating slope in each phase (slope= -0.85 for phase A1, -0.96 for phase B1, -0.2 for phase A2, and -1.4 for phase B2). **Overlap:** Because the mean frequencies and trends were very similar for the latter three study phases, there was considerable overlap between data points in these phases. Specifically, 2 points overlapped between phases A1 and B1, while all the data points overlapped between phases B1 and A2 and between A2 and B2. **Stability:** Data for this participant were very stable; stability in phase A1 was 87.5% and phases B1, A2, and B2 were all 100% stable.

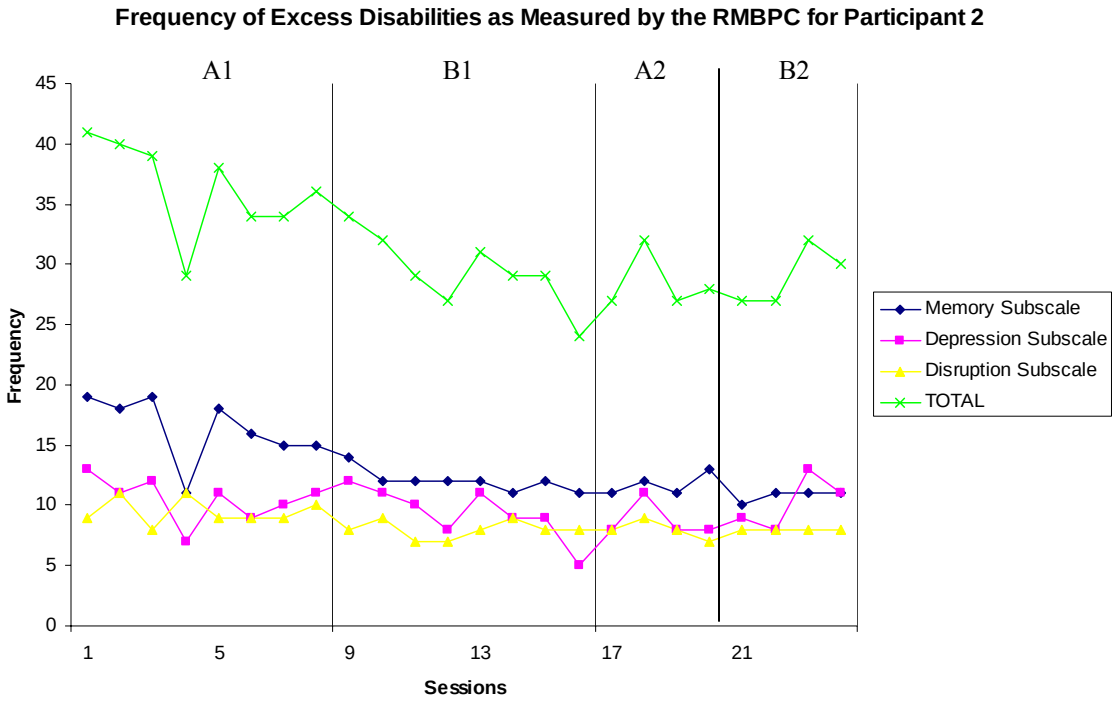


Figure 4-14. Frequency of excess disabilities across sessions for P 2, as rated by the CG, on the RMBPC.

Figure 4-14 shows that excess disabilities were more frequently reported on the memory subscale (means for phases were: 16.25 for phase A1, 12 for phase B1, 11.75 for phase A2, and 10.75 for phase B2), while the depression and disruption subscales showed approximately the same frequency of excess disabilities (means for the depression subscale: 10.5 for phase A1, 9.38 for phase B1, 8.75 for phase A2, and 10.25 for phase B2; means for the disruption subscale: 9.5 for phase A1, and 8.0 for phases B1, A2, and B2).

Participant 3

The frequencies of excess disabilities over the course of the study as rated by the CG for P 3 are displayed in Figure 4-15. In general, the frequency of excess disabilities for P 3 remained fairly constant throughout the course of the study. **Mean:** There was

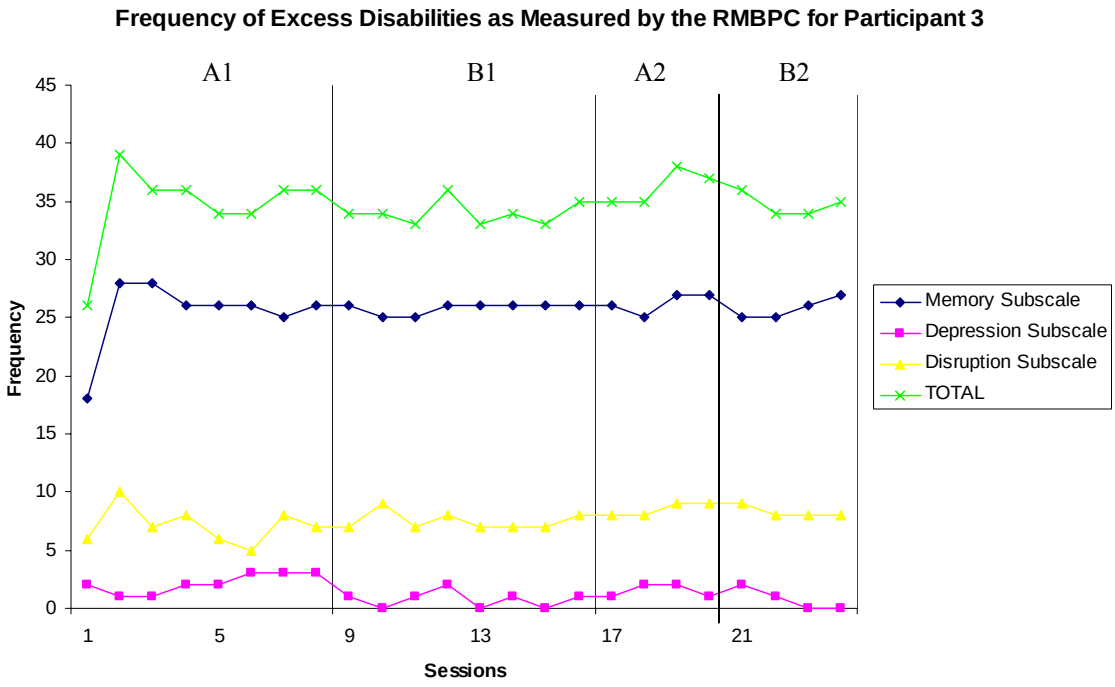


Figure 4-15. Frequency of excess disabilities across sessions for P 3, as rated by the CG, on the RMBPC.

little observable change in phase means (34.63 in phase A1, 34 in phase B1, 36.25 in phase A2, and 34.75 in phase B2). **Latency:** As there was not much change in means, there was little evidence for quick changes in latency. While there was a 2 point decrease and a deceleration of the trend (slope= 0.56 to 0.02) between phases A1 and B1, there was no level change between phases B1 and A2, although the trend did accelerate (slope =0.9) through phase A2. Finally, there was a one point decrease and a deceleration of the trend (slope= -0.3) between phases A2 and B2. **Overlap:** Again, there was substantial overlap between data points in these phases (all points between phases A1 and B1, and half the points between phases B1 and A2, and phases A2 and B2). **Stability:** The data for this participant were very stable, with 75% stability in phase A1 and 100% stability in each of the other phases.

Figure 4-15 shows that for P 3 memory problems were by far the most frequent domain for excess disabilities (means for phases were: 25.38 for phase A1, 25.75 for phase B1, 26.25 for phase A2, and 25.75 for phase B2). Excess disabilities related to disruption were the next most frequent with phase means of 7.13 for phase A1, 7.5 for phase B1, 8.5 for phase A2, and 8.25 for phase B2. Finally, excess disabilities related to depression were not a frequently rated problem by the CG for P 3 (phase means: 2.13 for phase A1, 0.75 for phase B1, 1.5 for phase A2, and 0.75 for phase B2).

PADE Part III Subscale Score

Part III of the PADE measured excess disabilities related to problems with physical function. The CGs were asked daily to answer 10 questions related to the physical functioning of the participants. Scores ranged from 1 to 4 for each item, for possible total subscale scores ranging from 10 to 40, with higher scores representing higher excess disability related to physical functioning.

Figure 4-16 shows the mean frequencies of physical functioning excess disabilities for each participant. For P 1, there is a gradual decrease in means over the course of the study (18.25 in phase A1, 16.88 in phase B1, 15.5 in phase A2, and 13.25 in phase B2). For this participant, daily performance was variable throughout the study with a range from a low rating of 11 to a high of 24. For both P 2 and P 3, there was initial variability in phase A1 (scores ranging from 17-23 for P 2 and 13-18 for P 3). At the beginning of the first treatment phase, CG ratings of physical function stabilized and remained this way for the remainder of the study (range of scores from 19-22 for P 2 and 14-16 for P 3). This is reflected in the stable phase means for these two participants. Means for P 2 were as follows: 20.63 for phase A1, 21 for phase B1, 20.5 for phase A2, and 20.25 for

phase B2. Means for P 3 were: 15.38 for phase A1, 16.0 for phase B1, 14.5 for phase A2, and 14.75 for phase B2.

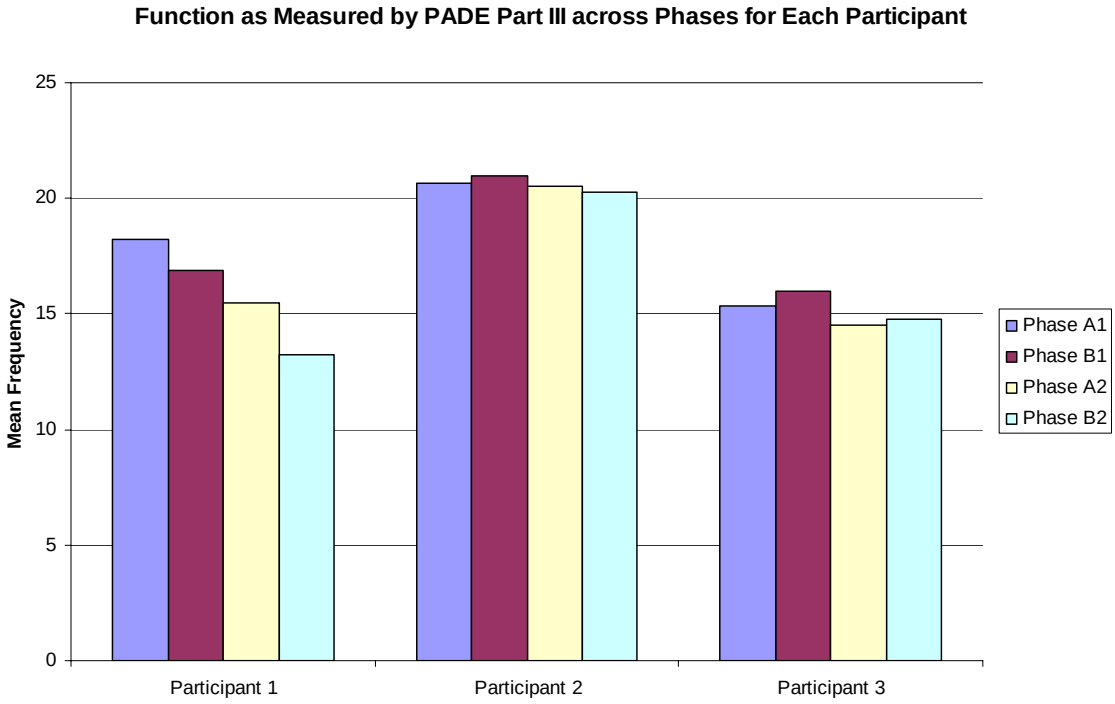


Figure 4-16. Mean frequencies of excess disabilities related to physical functioning, across phases, for all participants.

Reliability of Caregivers' Ratings of Pain Behaviors

The third specific aim of this study was to determine the reliability of CGs' ratings of pain behaviors in the participants with dementia. This was done by calculating Pearson's *r* between CGs' and trained TOs' ratings on Part I of the PADE. This measure was completed daily by both the CG and the TO. The intent was for both observers to watch the 10-minute activity protocol completed by the participant and independently complete this portion of the PADE based on that 10-minute observation. The correlation coefficients for each CG versus the TO's are presented for each phase, and for the total study, in Table 4-4. The relationship between the CGs' and the TOs' ratings are also

shown in scatterplots for each participant (See Figures 4-17 through 4-19). The CGs' and TOs' frequency ratings on this measure are presented in Figures 4-10 through 4-12.

Table 4-4. Caregiver and Trained Observer PADE Part I Correlations across Participants for each Phase and for the Total Study

Participant	CG v TO Phase A1	CG v TO Phase B1	CG v TO Phase A2	CG v TO Phase B2	CG v TO Total Study
P 1	.34	.90**	.58	.87	.82**
P 2	.41	---	---	-.52	.26
P 3	.76*	.09	.29	.88	.45*

CG= Caregiver, TO= Trained Observer
*correlation significant at the .05 level (2-tailed)
**correlation significant at the .01 level (2-tailed)
---correlations not calculable due to constant values

For P 1, the CG's and the TO's ratings were significantly correlated for phase B1 (r = .90) and for the total study (r = .82). There were no significant correlations between the CG's and the TO's ratings on part I of the PADE for P 2. Correlation coefficients were not calculable for half of the study phases for this participant, as the CG's ratings were constant, at a frequency of 20. For P 3, the CG's and the TO's ratings were significantly correlated for phase A1 (r = .76) and for the total study (r = .45).

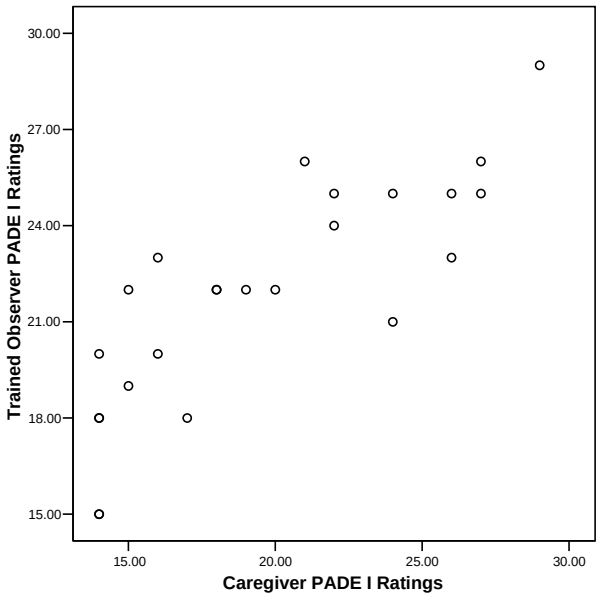


Figure 4-17. Scatterplot for the CG's and the TO's total scores on PADE Part I for P1.

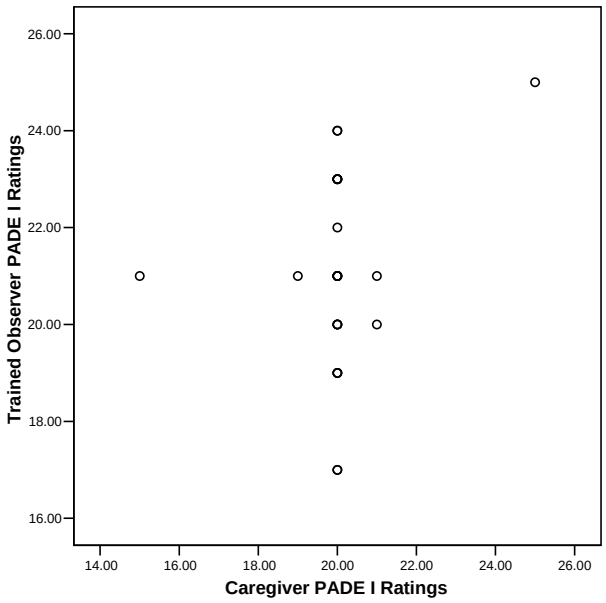


Figure 4-18. Scatterplot for the CG's and the TO's total scores on PADE Part I for P2.

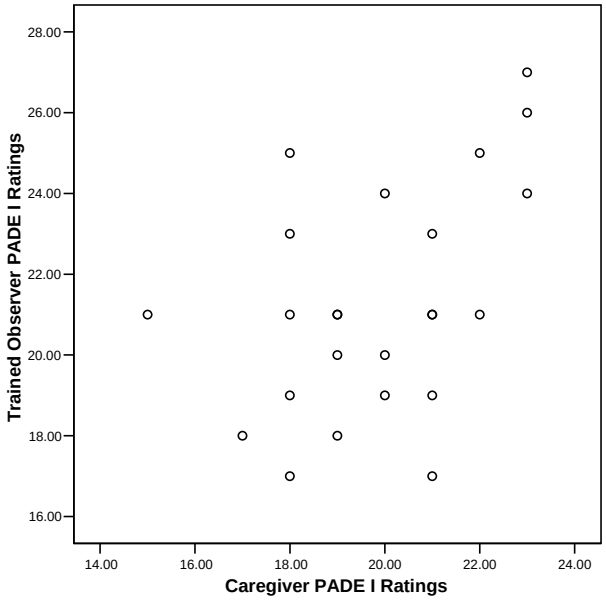


Figure 4-19. Scatterplot for the CG's and the TO's total scores on PADE Part I for P3.

Pain Behaviors Frequently Displayed by Persons with Dementia

The fourth and final aim of this study was to investigate which pain behaviors were most frequently displayed by persons with dementia. Three measures were used to determine which behaviors were displayed with the highest frequency. First, were the

coded video-taped activity protocols, next were the caregiver's ratings on Part I of the PADE, and finally, were the free-response answers given by the CGs regarding which behaviors they have noticed that indicate pain.

Frequent Pain Behaviors determined by the Coded Activity Protocols

There were nine pain behaviors of interest coded from the activity protocols. (See Table 3-2 for definitions of these behaviors). Of these nine behaviors, four were more coded more frequently across all participants than the others. These four behaviors were guarding, bracing, shifting, and sighing/nonverbal expressions. Figure 4-20 displays the total combined frequencies of all nine behaviors across all participants.

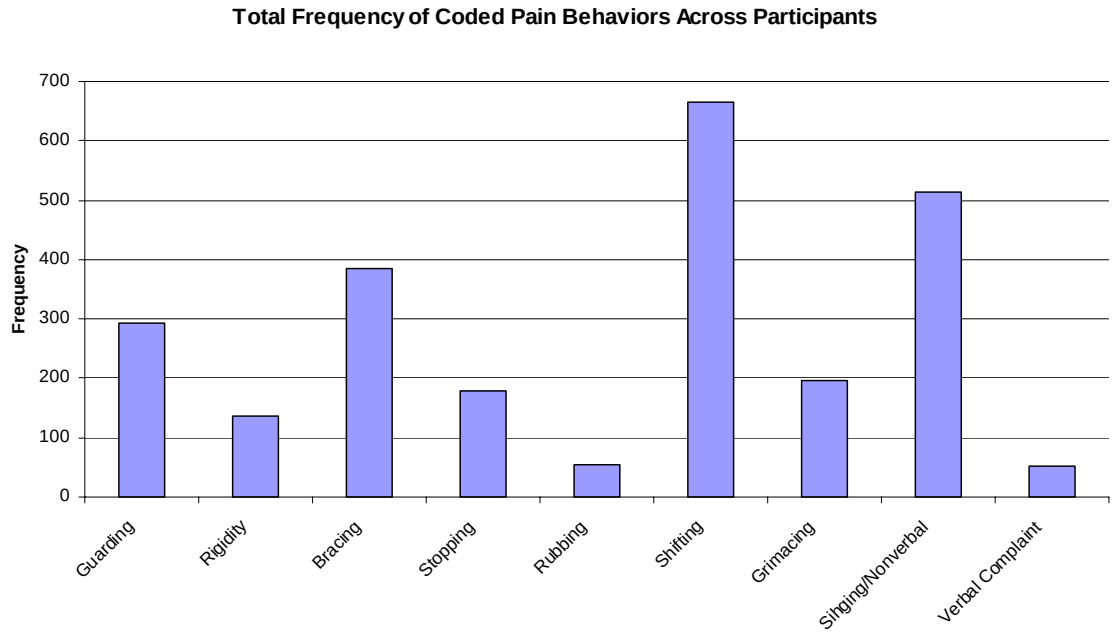


Figure 4-20. Total frequency of pain behaviors coded from the activity protocols across all participants, highlighting the most frequently displayed pain behaviors.

Frequent Pain Behaviors determined by Caregivers' Ratings on Part I of the PADE

Part I of the PADE is further broken-up into four categorizations of pain expression: facial expressions, posture, vocalizations, and breathing. Of these four

categories, two had higher frequency ratings from the caregivers. These categories were facial expressions and posture. Figure 4-21 displays the total combined frequencies for all four categories across all participants.

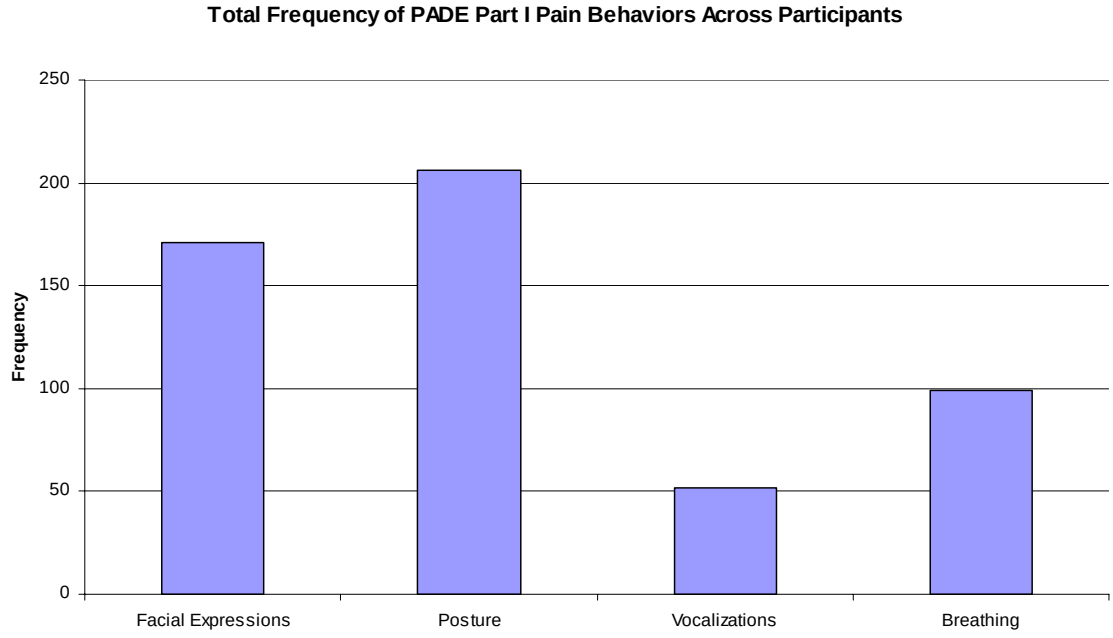


Figure 4-21. Total frequency of PADE Part I pain behaviors across participants, highlighting the most frequently recognized pain behaviors by CGs.

Frequent Pain Behaviors reported by Caregivers on the Free Response Question

A free response question was included in the daily measures which asked caregivers "What pain behaviors did you notice that were most representative of pain in the participant today?" Although responses varied between CGs, and frequently, there was no response, several themes emerged across caregivers. Each CG reported that their loved one verbally reported the presence of pain. Two CGs reported that their loved one had episodes of crying. All CGs expressed that their loved one physically signaled that they were in pain. Examples of this included: holding their back after walking, taking several attempts to stand up from a chair, stiffness and rigidity, walking slower and more

carefully, grabbed knee, and painful facial expressions. Two CGs also reported that their loved one got up during the night, and one CG reported that her loved one ate less.

CHAPTER 5
DISCUSSION

This feasibility study evaluated the effect of acetaminophen on reducing observable pain behaviors in persons with dementia, as assessed by both trained observers and the participant's primary caregiver. This innovative study extends previous research findings as it is one of the first studies to investigate and produce evidence for the effectiveness of an analgesic trial in reducing pain behaviors in community-dwelling persons with dementia. This study also attempted to provide evidence that providing continuous pain relief could reduce the frequency of excess disabilities that often accompany dementia and that are exacerbated by chronic untreated pain, an idea that has been postulated in the literature, but has only been formally tested in a few studies. Another important aspect of this feasibility study was that it is one of a minority of studies providing evidence that primary caregivers of community-dwelling persons with dementia could serve as reasonable proxy raters of their care recipient's pain. Finally, the most frequently displayed pain behaviors by persons with dementia from this study were compiled with findings from previous investigators in an effort to educate dementia caregivers on commonly displayed pain behaviors.

While the results of this feasibility study support previous research that has advocated for the use of an analgesic trial in reducing pain (Buffum et al., 2001; Douzjian et al., 1998; Herr et al., 2006; Horgas, McLennnon, & Floetke, 2003) and excess disabilities in persons with dementia (Allen et al., 2003; Buffum et al, 2001; Douzjian et al.; Shega, Hougham, Stocking, Cox-Hayley, & Sachs, 2005;); the study results should be

appraised in regards to the feasibility nature of the present study. The study also supports previous findings that older adults with dementia do experience pain (Herr et al.) and further, it shows that it can be amenable to treatment. Previously, most research on pain assessment in persons with dementia and the few studies that have included a pain treatment component have been carried out in nursing home or hospitalized populations (Herr et al.). To this author's knowledge, this is one of the first studies to investigate a treatment for chronic pain in community-dwelling persons with dementia. Studies of this nature are necessary as previous researchers have demonstrated that persons with dementia have unique and serious barriers to accurate pain assessment, placing them at high risk for nondetection and undertreatment of their pain (Chinball et al., 2005; Herr et al., Horgas & Tsai, 1998).

Effect of Acetaminophen on Self-Reported Pain Intensity and Observable Pain Behaviors

Pain in this study was measured through assessments by trained observers of pain behaviors during an activity-based protocol performed by the participant with dementia. Trained observer and caregivers both rated pain behaviors on a pain measurement tool (PADE Part I). Participants were also asked to self-report their pain intensity both immediately preceding and following the activity protocol. Again, it is important to remember that each of the three participants received that maximum number of doses of the pain treatment during waking hours in each of the intervention phases in an effort to provide continual pain relief.

Self-Report of Pain

Participants were asked to self-report their pain using the numeric rating scale before and after performing the activity protocol. While many researchers have found

that persons with dementia can reliably self-report pain, most have found that this ability decreases as the severity of dementia increases (Pautex et al., 2005; Weiner, Peterson, Logue, & Keefe, 1998), and all three participants in the present study had severe dementia. In fact, of the three participants with dementia in this study, two were initially screened as having moderate dementia on the MMSE (scores of 10 and 18), while the third had severe dementia (score of 5). Upon further cognitive testing, all three participants were found to be severely cognitively impaired based on their performance on the DRS-2. (This was also true for the two participants who began but later were withdrawn from the study).

Over the course of the study (i.e. 24 sessions each with two occasions of self-report, for 48 total occasions where self-report was elicited), P 1 responded "No" when asked "Are you having any pain right now?" for all occasions. P 2 used the NRS on four occasions (with this being on both occasions at 2 sessions during the final treatment phase) to self-report mild pain intensity (scores of 1s and 2s on the NRS). P 3 used the NRS on six occasions (twice for both occasions at a session and twice preceding the activity protocol only) to self-report pain intensity. On five occasions, during both the baseline and treatment phases, this pain was mild (1s and 2s on the NRS) and on one occasion during the initial baseline phase, this pain was moderate (6 on the NRS). These findings support the fact that self-report alone cannot be used to assess pain in this population, as for the majority of occasions for each participant, they either responded that they were not having any pain at that moment, or they were unable to use the measurement tool. Lending further support, are the findings of Buffum and colleagues (2001) who showed that verbal capacity did not guarantee the ability to report pain

intensity. This could also weaken the assessment of pain treatment strategies in that their effectiveness may go undetected if the assessment measure itself is not reliable (Chinball et al., 2005).

In contrast, this author found two studies that do not advocate the routine use of observational scales in demented patients. Pautex and colleagues cite that in their study, the majority of persons with dementia were capable of self-report. Furthermore, Jones, and colleagues (2005) assert that only one-half of their nursing home sample participants (both cognitively intact and impaired) who self-reported having pain actually displayed any pain behaviors. Therefore, by using only observational methods, pain would have gone unnoticed in half of their sample. However, the self-report data from the present study supports the assertion that both observational methods and proxy pain assessments were necessary, in lieu of reliable participant self-report, to detect pain and the effectiveness of the intervention in this population. This method is supported by Cohen-Mansfield (2002) who asserts that "in the absence of a gold standard, consistencies between assessments of different sources and between findings for the mildly impaired and the severely impaired can be used as approximations which will help clarify the evasive construct of pain in cognitively impaired individuals" (p. 563).

Observation of Pain Behaviors

Pain behaviors were assessed by observing the participants perform an activity-based protocol. Both the frequency and duration of pain behaviors were evaluated. For each of the three participants, both the frequency and duration of pain behaviors declined in the treatment phases as compared to the baseline phases. These declines were found to be robust through graphical analyses of the data, looking at changes in mean, latency, overlap, and stability. Specifically, the mean frequencies of observed pain behaviors, as

well as the mean duration of pain behaviors decreased in each participant in both the initial and follow-up treatment phases (B1 and B2) of the study. The latency of change (assessed through level and trend changes) was moderately quick across participants. While changes in level were generally always large and in the intended direction (i.e. decreasing while entering treatment phases and increasing while entering baseline phases), trend changes were in the intended direction approximately half of the time (i.e. decreasing or flattening of the slope in treatment phases, and increasing slopes in baseline phases). This suggests that the latency of change in pain behaviors may be more gradual and may not respond immediately to treatment. However, there was little overlap between phases, suggesting that acetaminophen was able to produce real changes in pain behaviors, as the majority of the true frequencies and durations of pain behaviors were clearly different between study phases. Furthermore, there was good stability (generally from 62.5% to 100% within phases) in the frequency of pain behaviors in each participant. This is somewhat unexpected as pain is thought to be labile in nature (Werner et al., 1998). It is not surprising then that the duration of pain behaviors were mostly unstable (i.e. not within 15% above or below the phases' trend line), ranging from 0% to 75% stability within phases. This may suggest that the amount of time a person exhibits a specific pain behavior is more variable than the actual occurrence of that behavior.

Overall, the findings from this feasibility study support the use of routine dosing of acetaminophen in the form of Tylenol Arthritis (1.3 g at least twice per day) for the treatment of chronic osteoarthritis pain in community-dwelling older adults with dementia. This differs from the findings of Buffum et al., 2004 who saw no difference in

discomfort scores between scheduled and prn use of acetaminophen. However, the measurement tool employed in their study assessed discomfort which may not truly represent pain. Additionally, this study supports the current treatment guidelines which all recommend acetaminophen as the first choice analgesic when treating mild to moderate pain (American College of Rheumatology, 2000; AGS, 2002; British Medical Journal, 2000; European League Against Rheumatism, 2003). An important contribution of the present study is that is extends this recommendation to elders with dementia, a subpopulation of older adults for whom no specific treatment guidelines exist.

Proxy Pain Assessments

The second method of assessing participants' pain behaviors was through using part I of the PADE measurement tool, which both the caregiver and the trained observer completed daily after observing the participant perform the activity protocol. Overall, for P 1 and P 3, both the caregivers' and the trained observer's ratings indicated that acetaminophen produced an observable change in participant behaviors. However, the changes seen with ratings on this measure were less dramatic than with the observational method. While changes in the mean scores on the PADE were higher in baseline phases than in treatment phases, both the latency of change (indicating how quickly a change in behavior was seen upon entering a new phase) and the overlap of data were less convincing. Interestingly, for P 2, the caregiver remained stagnant in her ratings of pain behavior on this tool for sessions 8-23. While this potentially could reflect her true observations, these ratings did not correlate with the trained observer's ratings for these sessions. It is possible that the caregiver became disengaged from the measurement tool and process or that she was no longer using the tool correctly.

Another possible explanation for the findings on this measure is that this particular tool did not capture the behaviors that were affected by the administration and withdrawal of the analgesic in a comparable manner to the observational method. Furthermore, the scoring on the PADE ranges from 1 to 4 on most questions, leaving little room to see anything other than major changes in behavior (i.e. from extreme to never occurred). This could also explain why the stability of pain behaviors as rated on this tool were high (ranging from 50-100% for P 1, 100% for P 2, and 87.5-100% for P 3). The scoring of this measurement tool has been a focus of recent critique (Herr et al., 2006).

The findings from this study suggest the observational measure of pain behaviors was more sensitive to picking up changes in behavior than were the trained observer and caregiver ratings of pain behavior using the PADE. This is an important finding because while neither method has been highly correlated with self-report in persons with dementia, in the absence of reliable self-report these are some of the only options for pain assessment. Recently, Pautex and colleagues (2005) found self-reported pain in hospitalized persons with dementia to be moderately correlated with an observational rating system (Doloplus) completed by their nurse. In a review of studies using observational methods to assess pain behavior, Labus and colleagues (2003) estimated a mean overall effect size of 0.26 for the correlation between observed pain behaviors and self-reported pain intensity ratings. They also found that the global composite measures of pain behaviors showed stronger associations with self-reported pain intensity than did individual pain behaviors. While not strong, these findings suggest that observational

methods are at least moderately correlated with self-reported pain in persons with dementia.

Effect of Acetaminophen on Excess Disabilities

In the present study, excess disabilities were rated by the caregivers using both the RMBPC and the PADE. The range of total frequency of excess disabilities was similar for each participant, generally between ratings of 25-45 on the RMBPC (possible range = 0- 96) each day over the course of the study. This moderately high frequency of excess disabilities may be attributed to the severe cognitive impairment in each of the participants. This is similar to the findings of Shah, Ellanchenny, and Suh (2004), as well as Volicer and Hurley (1998) who found higher frequencies of excess disabilities in persons with lower cognitive scores. However, McCarty and colleagues (2000) found that, in patients with very severe dementia, excess disabilities decreased in frequency over a 2-year follow-up as participants became more globally impaired.

In general, there was not a large change in the frequencies of excess disabilities as rated on the RMBPC or the PADE. For P 1 and P 2 there was an initial decrease in caregiver rated excess disabilities on the RMBPC during the first treatment phase that remained throughout the remainder of the study. Also for these two participants, while there was good level change between study phases, the trend was less responsive to change in study phases, suggesting that there was a slow latency of change in excess disabilities in response to the acetaminophen, meaning that the frequency of excess disabilities did not change quickly in response to continual pain relief. However, it is also possible that the participants' behaviors during the initial baseline phase reflected their reaction to their involvement in the research study, which could have been an increase in their usual levels of excess disabilities. This could mean that the decrease

seen in the initial treatment phase, which remained for the rest of the study, was actually a return to their normal levels of behavior once their period of reactivity subsided. Only for P 3 was there an increase in the frequency of excess disabilities during the return to baseline phase (A2) which actually surpassed original baseline levels. Also, for P 3, there were good level and trend changes highlighting a more rapid response to the acetaminophen in decreasing the frequency of excess disabilities; however, because the frequency of excess disabilities in the second baseline phase (A2), surpassed original baseline levels, the influence of extraneous factors in producing this change cannot be ruled out. However, there was excellent stability (75% to 100% within phases) for this participant which makes it less likely that this increase was related to an outlying score (i.e. if the frequency of excess disabilities for one session had been much higher than for the other sessions in that phase). Finally, there was high overlap between phases in RMBPC scores for all participants, again suggesting that there was not a large response in excess disabilities to the administration of acetaminophen. More importantly, these findings suggest that the return to baseline phase (i.e. 4 sessions) may not have been long enough for pain to cause an increase in the problem behaviors to return to baseline levels. On the other hand, this also suggests that routine dosing of acetaminophen may have a lasting effect on alleviating problem behaviors.

Another interesting finding was that the most frequent behavior problem domains (i.e. memory, depression, and disruption) were rated differently between the participants, with the depression domain rated as being the most frequent in P 1, while the memory domain was rated the most frequent in P 2 and P 3. This differs from the findings of Horgas and Margrett (2001) who found the highest prevalence rates of behavioral

problems to be on the disruptive domain of the RMBPC in nursing home residents. Also, only for P 1 was any kind of improvement seen on the function measure (PADE part III). In this participant, the function scores on the PADE continually decreased over the course of the study, while function scores for P 2 and P 3 remained nearly the constant. This may be attributable to the fact that the caregiver for P 1 was notably impressed with her mother's improved ability to perform the walking portion of the activity protocol when she was taking the treatment drug. This is similar to the findings of Logsdon and colleagues (2002) who suggest that caregivers of persons in the later stages of dementia are more attuned to ADL changes than other behaviors (i.e. IADL changes or behavioral disturbances).

Previous researchers have supposed also that pain dampens activity and restricts social engagement, leading to increased depressive symptoms (Chinball et al., 2005). Likewise, Volicer and Hurley (2003) report that unrecognized and untreated pain is the most common physical cause of abnormal behavior. While there was an overall trend for the frequency of excess disabilities to decline over the course of the study, it is possible that the time frame of the study was not long enough to establish continuous pain relief that would enact a change in excess disabilities. Supporting this are the results obtained by Chinball and colleagues who found that continuous administration of acetaminophen over the course of 4 weeks improved nursing home residents with dementia's social engagement and decreased their time spent performing self-care tasks. However, these researchers did not find that acetaminophen administration had any effect on participants' aggression or emotional well-being, suggesting that perhaps these excess disabilities are not related to untreated chronic pain, or that acetaminophen was not a strong enough

analgesic to produce change in these factors. Douzjian and colleagues (1998) also found that continuous administration of acetaminophen was able to decrease excess disabilities to the extent that antipsychotic drug use was reduced from 20% to 0%, and antidepressant usage decreased to 23% in their institution. However, Buffum and colleagues (2004) saw no greater effect of scheduled doses of acetaminophen (2,600mg/d) for two weeks on measures of discomfort (including agitation) in severely impaired nursing home residents with dementia than were found for prn doses. Again, this argues for a longer trial of acetaminophen before measurable changes in excess disabilities may be observed.

Furthermore, none of the participants were found to have depression at baseline measures, so there was not much room for improvement in this particular domain. However, it is possible that the measurement tool for depression, the short-form of the GDS, may not have been sensitive enough to detect actual depression in this sample, as the original GDS has been found to be less valid in persons with higher levels of cognitive impairment (Holroyd & Clayton, 2000). Also, depression in general, has been found to be less frequent than other excess disabilities, occurring only in 11-24% of persons with dementia (Espiritu et al., 2001), and previous researchers have concluded that pain control alone will not relieve depression in the elderly (Douzjian et al., 1998). This may also contribute to the explanation of the relative lack of improvement in functional performance in two of the participants, as higher rates of depression have been found to be significantly correlated with lower functional performance (Espiritu et al.). In addition, the small improvement in excess disabilities may be related to the fact that two of the participants (P 1 and P 2) were taking at least one prescribed antipsychotic medication targeting these behaviors. Although not strong, the results of this feasibility

study lend support to the notion that chronic untreated pain contributes to the frequency and severity of excess disabilities that often occur in persons with dementia.

Reliability of Caregivers' Ratings of Pain Behaviors

Taken together, findings from previous studies have shown that family caregivers have been somewhat better than other proxy raters (i.e. physicians, nurses or nursing assistants) at estimating their care recipients' pain, usually erring on the side of overestimating the intensity of the pain (Ferrell, 2001; Herr et al., 2006, Shega et al., 2004; Werner et al., 1998). Furthermore, caregivers in general are better at detecting the presence of pain than actually estimating the intensity of the pain in cognitively impaired persons. In the present study, 2 of the 3 caregivers' pain assessments were found to be significantly correlated with the trained observer's assessments (r = .45 to .82). (Correlations between CG 2 and the trained observer were affected by this caregiver's constant rating on the PADE for sessions 8-23). This shows promising results when compared to those of Feldt, Warne, and Ryden's (1998) study where only 47% of nursing assistants' and family members' ratings of an individual's pain agreed. The present study found similar results to those obtained by Krulewitch and colleagues (2000) in which 67% of nonprofessional caregivers and their care recipients agreed as to the level of pain experienced by the care recipient with dementia. This suggests that the steps taken to increase caregiver reliability in this study (i.e. training on the measurement tools and timing pain assessments to occur during the activity protocol) were moderately successful.

In order to further evaluate the reliability of the caregivers to report pain and excess disabilities in their care recipient, it is important to consider both caregiver and care recipient characteristics that have been shown to influence reports of pain. Several

studies have also found that certain characteristics in the person with dementia influence their caregivers' proxy report of pain. These characteristics include levels of agitation, well-being, cognition, and depression (Cohen-Mansfield, 2002; Horgas & Dunn 2001; Shega et al., 2004; Shega et al., 2005). Furthermore, Shega and colleagues (2005) found that caregivers who were depressed had a nearly three-fold increase in the likelihood of reporting pain in their care recipient. Caregiver 1 was the only participant in the study to be screened as depressed and her level of depression did increase over the course of the study. This may explain why P 1 had higher frequency ratings on the depression domain of the RMBPC than the other two participants. (This increase was discussed with the caregiver by the PI. This caregiver recognized that she did at times feel depressed about the situation, as she was unsure that she was doing the best she could for her mother. With the support of her family and by enrolling her mother in an adult day-care program, she felt that she was taking the right steps towards caring for her mother and for herself). However, all of the participants were rated to have similar levels of both pain behaviors and excess disabilities. Also, caregiver 1's ratings were significantly correlated with the trained observer's so it is unlikely that her depression had a large, if any, effect on her ratings of participant behavior.

Cognition is also thought to influence caregiver reports of pain, in that higher levels of impairment are associated with less intense caregiver pain ratings (Cohen-Mansfield, 2002). Each of the participants in the present study were severely cognitively impaired, so it is possible that their caregivers under-reported their pain intensity. This may explain why there was a trend for caregivers to rate lower frequencies and severities of pain in the participants than the trained observer, however, as previously mentioned, caregiver and

trained observer reports were significantly correlated for 2 of the 3 pairs. These findings argue that caregivers' ability to report pain, although flawed, could be superior to other measures because their long-term intimate knowledge of the person may enable them to better interpret the persons external cues of pain (Cohen-Mansfield).

Pain Behaviors Frequently Displayed by Persons with Dementia

The most frequently observed pain behaviors displayed by the participants in the present study were identified through the coded activity protocols, caregivers' responses on the PADE part I, and caregivers' responses to an open-ended questionnaire asking them to identify behaviors that signaled pain to them. Of the nine behaviors coded for on the observed activity-protocols, four were more coded more frequently across all participants than the others. These four behaviors were guarding, bracing, shifting, and sighing/nonverbal expressions. This is similar to previous findings were guarding, shifting, and bracing were the most frequently observed behaviors in both cognitively intact and impaired elders with chronic pain (Horgas, 2001). Additionally, according to caregiver responses on the PADE part I, the most frequent pain behaviors were identified through facial expressions and posture. This is similar to the finding of Jones and colleagues (2005) who found that upon observing participants during movement, the most frequently displayed behaviors included facial movements, nonverbal indicators, and bracing. Furthermore, Cohen-Mansfield and Creedon (2002) found that nurses cited facial grimacing, agitation, touching a body part, and nonverbal expressions to be the most frequent behavioral indicators of pain in noncommunicative nursing home residents.

Several common themes emerged when caregivers were asked to identify the behaviors that their care recipient displayed that signaled pain. These included: their loved one verbally reported the presence of pain; their loved one had episodes of crying;

their loved one physically signaled that they were in pain (e.g. held their back after walking, took several attempts to stand up from a chair, displayed stiffness and rigidity, walked slower and more carefully, grabbed knee, and displayed painful facial expressions). Two caregivers also reported that their loved one got up during the night, and one caregiver reported that her loved one ate less. These caregivers' responses are similar to those found by Weiner and colleagues (1999) who found that the use of mechanical help, shifting weight when seated, taking or asking for pain medication, moving or walking in a protective fashion, moving extremely slowly, limping, lying down, bracing when seated, clutching the painful area, stiffness, and asking someone to do something to help the pain, were the most salient pain behaviors in nursing home residents. More importantly, these behaviors were those for which the residents and caregivers agreed.

Validation of the Study Findings

Treatment Integrity

In any interventional study, the integrity of the intervention must be evaluated. The goal of the intervention in the present study was to decrease observable pain behaviors and excess disabilities in community-dwelling persons with dementia. In order to evaluate treatment integrity, the researcher must ensure correct implementation of the treatment, as well as systematically evaluate the treatment outcome with psychometrically sound measures of the target behavior(s) (Horgas et al., 2003). In the present study, the treatment was in the form of Tylenol Arthritis medication. Treatment implementation was evaluated in several ways. First, the principle investigator established that the participant could swallow orally administered pills. Second, a dosing schedule was created with the aid of the caregiver in order to establish a minimum of two

times during a 24-hour period (at least 8 hours apart) that the participant would be awake to take the treatment. Additionally, caregivers were asked to document on daily medication logs (provided by the PI) the time that all medications, including the treatment drug, were administered to the participant and to note if any doses of any medication were missed. Treatment implementation was not, however, assessed by counting the pills in the bottle to ensure that the treatment was given; rather, caregivers were trusted to report accurate dosing frequencies.

Treatment outcomes were evaluated using instruments that have previously been validated for assessing the target behaviors in this population (Horgas, 2001; Keefe & Block, 1982; Teri et al., 1992; Villanueva et al., 2003). Ideally, these measures would have been validated through participant self-report, however, as previously described, self-report is considered to be unreliable in persons with dementia. However, the inter-rater reliabilities between two caregivers and the trained observer were significantly correlated, and inter-rater reliabilities on the coded activity protocol between two trained observers (one blind to the study phase of the videotaped session) were very good (K= 0.80).

Validity of the Findings

In order for research findings to be meaningful to the research and clinical practice communities, it is important to address the validity of the findings. Validity refers to "how true or accurately claims or important concerns are measured" (Elder, 1999, p. 106). Validity is increased by minimizing threats to internal, construct, and external validity. Internal validity is concerned with the ability to show that it was the study's intervention that was responsible for the outcomes versus other extraneous factors (Elder). Threats to internal validity in the present study were minimized in the following

ways. First, although the present study attempted to assess chronic pain in a naturalized setting (i.e. the participant's home), participants performed a standardized activity-based protocol consisting of ADLs in an effort to induce pain so that observable pain behaviors could be assessed. In fact, Labus and colleagues (2003) found that observational pain behavior methods conducted in naturalistic settings had higher effect sizes than did those conducted in a standardized setting. Second, these protocols were videotaped to increase internal validity by: allowing the researcher to observe the participants' behavior on a more controlled time-frame, allowing a second observer to code the tapes for reliability, and allowing the researcher to detect possible extraneous variables in the environment captured on tape (Elder). Third, although there was a potential for caregiver reactivity because the study was conducted in their residence, each caregiver was trained on how to use the measures. Also, because the study was conducted daily for several weeks, the caregivers quickly became accustomed to the PI or trained observer being in their home. However, the potential for subject reactivity can not be overlooked. It is possible that the participants with dementia in this study reacted to the presence of the research team in their home and that their normal behaviors were affected. It was for this reason that the initial baseline phase lasted for so many sessions in order to combat initial reactivity.

Construct validity is concerned with an "instrument's ability to measure the constructs of interest" (Elder, 1999, p. 107). Threats to construct validity were minimized in the present study by clearly defining the pain behaviors of interest and by training both the caregivers and the trained observers on how to use the measurement tools. Additionally, each participant was selected on the basis that they had the presence of the particular problem addressed by the intervention, chronic osteoarthritic-type pain.

This increases construct validity by ensuring that the participants had the target pain behaviors to begin with so that the intervention effect could truly be measured (Zarit, Stephens, & Femia, 2004). Threats to external validity refer to "factors that restrict or limit the ability to generalize the cause and effect relationship demonstrated in a given experiment to and across populations of people, settings and operational representations of treatments and outcomes" (Zarit et al., 2004, p. 219). In the present study, there is limited generalizability of these findings due to the small sample size and relative homogeneity of the sample (66% female, 100% Caucasian, 100% severe dementia, 100% osteoarthritic pain). In total, attempts were made to minimize threats to validity in the present feasibility study, and the findings therefore support the use of acetaminophen as an analgesic in community-dwelling persons with severe dementia and chronic osteoarthritic pain, albeit in a narrow portion of the elderly population.

Nursing Implications

In 1996, Hudson and Sexton reported that older adults rated pain management as one of the top priorities for nursing care. In 2004, Morley stated that the area of cognitive decline was one of the 10 hot topics in aging. Therefore, in an effort to provide evidenced-based care to older adults with cognitive declines, nurses need to be involved in research evaluating the effects of pain treatment strategies in this population. Clinically, nurses are the direct link between patient pain and pain relief. Nurses should be educated on appropriate assessment and treatment strategies in their elderly clients, including understanding how to assess and treat pain in persons with dementia. Its been stated that "improving the nurse's knowledge related to pain management and effective strategies to assess pain may directly affect the pain experience and ultimately affect patient care outcomes" (Rodriguez, 2001, p. 44-45). The clinical and empirical

consensus is that, in persons with dementia, pain should be assessed through a combination of the client's self-report and a proxy-report using observational strategies. While each observational strategy in existence is inherently based on the assumption that proxy reports accurately reflect the client's own, this claim has never been adequately validated in the literature (Herr et al., 2006). Therefore, it is appropriate within the field of nursing to seek to validate observational measures of pain assessment and evaluate the effectiveness of pain treatments.

Recently, an interdisciplinary team of researchers developed a new conceptual model for assessing pain in noncommunicative persons with dementia (Snow et al., 2004). A major factor in this model is that pain must be assessed through the observation of external signs. The strength of this model is that it attempts to circumvent the usual critiques of proxy assessments by including in the model the potential for method factors (i.e. construct characteristics, rater type, data collection methods, and assessment instruments) and rater factors (demographic characteristics, pain history, pain knowledge/beliefs, relationship with patient, and secondary gain) to influence the observation of the patient's external signs.

Nurses also have the unique role of providing both patient care as well as educating the family. Educating the family to assess for signs of pain in their loved one is an important contribution that nurses can make to increase the detection and treatment of pain in this population. Snow and colleagues (2005) developed the BODIES mnemonic to help caregivers convey pain related signs and symptoms by assessing the *B*ehaviors that the person displayed, how *O*ften and the *D*uration for which they occurred, their *I*ntensity, the *E*ffectiveness of treatment (if given), and anything that made the behaviors

*S*tart/*S*top. This work shows promise that by educating caregivers to be on the lookout for signs of pain, persons with dementia may begin to receive better pain treatment.

The caregiver's ability to assess and treat pain in their loved one has potentially far-reaching implications. As previously stated, researchers agree that the excess disabilities seen in persons with dementia may be exacerbated by untreated pain. These same behavioral problems have been shown to greatly influence caregiver stress, and often are associated with the caregiver's decision to institutionalize the person (Bedard, et al., 2005). Therefore, treating pain in persons with dementia has the potential not only to decrease the frequency and severity of excess disabilities, but to also decrease caregivers' burden, which may in turn lead to keeping the person with dementia at home for a longer time.

Another finding of the present study that is important to clinical practice is that there were no adverse events related to the continual administration of acetaminophen (Tylenol Arthritis). Similarly, Chinball and colleagues (2005) reported no adverse events and all normal post-study liver function tests in their study of continual administration of acetaminophen (3,000 mg/day) for 4 weeks. This supports the safety of using acetaminophen as a round-the-clock pain reliever in persons with severe cognitive impairments and chronic pain, rather than as a prn (as needed) pain reliever. Since nurses are the clinicians responsible for the administration of analgesics in the hospital and institutional settings, it may be beneficial to administer prn analgesics as round-the-clock medications, or alert the physician for the need to change the medication order. The benefit of administering analgesic medications on a continual basis in this population is that caregivers can begin to assess for treatment effectiveness and/or the need for a

change in treatment. This change in practice could lead to better pain management in persons with dementia, by providing continual pain relief and not missing signs of pain in this population.

It is also important for nurses to be aware of the potential for self-reports of pain in this population to be unreliable. In the present study, each of the three participants was unable to use the Numeric Rating Scale to self-report their pain. This argues both for the use of alternate self-report scales as well as observational techniques. Shega and colleagues (2004) found the Verbal Descriptor Scale to be useful in their study of community-dwelling older adults with moderate to severe dementia. Additionally, nurses need to routinely ask patients about pain and observe for pain rather than rely on spontaneous reports from patients with dementia. Furthermore, Shega and colleagues (2005) argue that by incorporating varied pain assessment methods, clinicians will obtain a more comprehensive picture of the individual's pain, thus decreasing the chance of missing pain in this population.

Clinical Significance

The results of this study contribute to the existing, although scant, literature on the effectiveness of acetaminophen in reducing pain in persons with moderate-to-severe dementia. This is clinically significant in that acetaminophen is regarded as the safest analgesic drug, having very low incidence of the adverse effects seen with stronger analgesic drugs such as NSAIDs or opiods. While this study did not show vast decreases in the frequency of excess disabilities in persons with dementia, other researchers have found a clinically relevant increase in activity and engagement and decrease in the severity of excess disabilities in persons with dementia who received continuous doses of acetaminophen (Chinball et al., 2005; Douzjian, 1998). This is important because the

risk-benefit ratio of using acetaminophen is better than that of antipsychotic medications, because there is "less potential for hypotension, falls, memory loss, and addiction; increased functional capacity to perform activities of daily living; and decreased potential for movement disorder" (Douzjian, p. 178). Furthermore, Logsdon and colleagues suggest that quality of life assessments can provide a way to determine whether an intervention made a clinically significant improvement in the patient's life. While no formal QOL measure was employed in this study, the caregivers' answers on the free response questions often indicated that their loved one would have days during the treatment phases where they seemed to be more engaged with them and their environment.

This study also supports the use of the observation strategy employed as it was able to distinguish changes in participants' pain behaviors during baseline and treatment phases. While changes in pain behavior measured with the PADE Part I were noticed in only 2 of the 3 participants, taken together these findings support the use of pain assessment tools that encompass a wide range of behaviors in order to enhance the utility of pain assessment for clinicians. This study suggests that more than one pain assessment measure may need to be employed to assess pain in each individual so to as not miss that individual's means of expressing pain.

Furthermore, the results of the present study support the use of Single-Subject design methodology in assessing clinically relevant changes in behavior in persons with dementia. Clinically significant changes are able to be observed with this methodology because multiple points of data are collected from the same participant over time, allowing the researcher to observe the intervention's effect as the study progresses. It is

possible with this design, to start, stop, or change interventions based on the participant's behavior during the course of the study. Thus, the effectiveness of the intervention can be assessed during the course of a study, rather than waiting for the conclusion of the study to look at treatment results. This allows the researcher to be able to gear interventions to the individual in an effort to create more clinically significant results for that participant.

Limitations

This study was designed to be a pilot study addressing the feasibility of several issues. It investigated an analgesic trial whose effects in the study population were previously unknown. Additionally, it applied a measurement tool (the PADE) to a group of informal caregivers with whom it had not previously been tested. It is not surprising then that this study does have limitations. These limitations include: difficulties with recruitment, small sample size, choice of measurement tools, and feasibility.

Recruitment

Because participants for this study needed to meet several inclusion criteria (i.e. age 65 or older, diagnoses of dementia and osteoarthritis, living in the community with a primary caregiver, and no contraindications to taking oral acetaminophen), finding this subgroup of the population proved to be challenging. Recruitment strategies included working with local chapters of the Alzheimer's Association to access caregiver support groups as well as to publicize the study in their newsletters. While this did allow access to the population of interest, some chapters were reluctant to allow research personnel into their support group meetings. Also, many of the caregivers attending these meetings had already placed their loved one in a long-term care facility. The PI also attempted to recruit participants from the neurology and memory disorder clinics at the University of

Florida. However, most of the patients attending these clinics in the fall of 2005 did not meet the criteria for the study, and those who did either screened out or declined to participate. This contributes to the selective nature of the sample as the caregivers in this study were highly motivated to learn about pain assessment in their loved one and may have been more attuned to their loved ones' displays of pain than other caregivers.

Other researchers have also encountered challenges in accessing this vulnerable population. Shega and colleagues (2004) suggest that community-dwelling persons with dementia and chronic pain may be hard to find because they may have fewer painful co-morbidities (i.e. may be healthier and have fewer causes of pain as they remain living in the community). Buffum and colleagues (2004) describe the difficulty of recruiting nursing home residents to participate in an analgesic trial with acetaminophen largely because they had more severe pain problems (i.e. neuropathic pain) that would be unresponsive to acetaminophen and because legal guardians were not willing to allow the participant to take part in the study. Therefore it is necessary to educate the family caregivers in the importance of pain assessment in their care recipient and to find alternative strategies to access this isolated subgroup of caregivers and care recipients.

Sample Size

Another limitation of this study is the small sample size (N=3). While the study was designed to observe daily changes over time in a small sample, the generalizability of the findings is potentially limited. Due to the relative homogeneity of the sample (as previously described), it would be difficult to generalize these findings to younger persons with dementia, other racial groups with dementia, or to persons with dementia with chronic pain from conditions other than osteoarthritis. Additionally, other researchers have found that pain expression can vary by the individual (Herr et al., 2006).

For example, one participant may have muted facial expressions while others have exaggerated facial expressions. This was the case for P 2 in the present study whose frequency of grimacing (7.4) was much higher than those for the other two participants (0.25 and 0.5). This potential confounder supports the thought that pain assessments in this population needs to be comprehensive and tailored to each individual person. The small sample size may have affected the findings as a more heterogeneous group may have produced different findings.

Tool Choice

It is possible that the measures employed in this study weren't sensitive enough to detect true changes in behavior in this population or that they did not assess a comprehensive set of pain indicators. Herr and colleagues (2006) state that choosing a pain assessment tool for use in persons with dementia should be based on "sound evaluation of the tool conceptualization, subject comparability, feasibility of tool administration and scoring, reliability, and validity" (p. 172). These factors were considered when selecting measures for use in the present study. However, there were no previously developed measures for use with a community-dwelling population, so the measures employed were being extended to an untested subgroup of older adults.

Since the development of this study, other researchers have evaluated and critiqued the PADE measurement tool. Herr and colleagues (2006) evaluated the PADE based on the factors mentioned above and found that for all but subject comparability (i.e. how subjects this measure was tested on compare to subjects in other similar investigations), evidence for this tool was insufficient and/or needed revisions; subject comparability evidence supported the need for further testing of the measure. Of ten total measures rated, the PADE was the third lowest ranked pain assessment measure. Another critique

was that this tool was based on the assumption that caregivers reliably rate the intensity of pain in older adults with dementia, for which evidence supporting this assumption has been lacking. However, this is the assumption for any proxy measurement tool. Also, for 2 of the 3 caregivers in this study, ratings on the PADE were significantly correlated with those of a trained observer. Additional problems with this measure encountered in the present study included the difficulty in scoring and interpreting the total score, use of retrospective and current-oriented questions, as well as the unclear impact of questions that could receive a zero score. Although flawed, the PADE is one of only two scales that address sensory, affective, and behavioral components of pain (Snow et al., 2004).

Feasibility

In summary, it is possible that the limitations of the present study may have had an effect on the end study results. However, since this present study was designed to be a feasibility study, it is important to evaluate these limitations in regards to the overall feasibility of the study. The first main limitation was subject recruitment, and this is a concern for future studies involving this population. Since the target sample for the present study was three caregiver and care recipient pairs and five total pairs were at one point enrolled, it was feasible to recruit this sample. However, since the two pairs that did not complete this study were withdrawn by the PI, there are concerns about the feasibility of the study protocol. One main concern was to make sure that the caregivers were capable of administering the treatment drug according to the protocol (i.e. at least 2 doses per day). One participant pair was withdrawn from the study for failure to consistently provide at least two treatment doses per day. However, the initial results from this subject (who completed the first two study phases, or 16 sessions, and received at least one treatment dose per day during the intervention phase) did show a decrease,

albeit small, in the mean number of pain behaviors (as coded from the videotaped activity protocols) from the initial baseline phase (29 behaviors) to the intervention phase (26.75 behaviors).

The present study also attempted to assess the feasibility of having informal caregivers use the PADE measurement tool. Based upon the discussion of the limitations of this tool above, the PADE was perhaps not the best tool to utilize in this population where large changes in chronic pain were not evidenced. In terms of the feasibility of the caregivers using the tool, it is important to note that none of the caregivers reported any problems with understanding or implementing this tool during the course of the study. However, CG 2 did rate constant levels of pain behavior throughout most of the study on this tool, suggesting a potential disengagement with either the tool or the assessment process.

Finally, this study evaluated the feasibility of conducting a longitudinal study consisting of at least 24 daily sessions to be completed during a maximum of 6 weeks in the care recipients' home. This study found that the caregivers who completed the entire study (24 sessions) did so within a range of 24-26 days; indicating that for these caregivers it was not too great of a burden to participate in this type of research study. In conclusion, although there were issues with feasibility, this study did find that in general, this population can be recruited to participate in research and that caregivers can reliably administer a pain treatment intervention as well as reliably assess pain behaviors in their loved ones. These findings support the need for further replications of this study

Future Directions

The promising findings of this feasibility study warrant further investigation in a larger, more diverse sample of older adults with dementia residing in the community.

Ancill (1995) asserts that drug studies involving only a few patients that show promising results are required before large-scale drug studies are established. A larger scale study could be conducted using a convenience sample of older adults (such as attendees of an adult day care center or a memory disorder clinic population) who could be tracked over time and that have primary caregivers who could both administer the intervention and assess patient behaviors.

Although the activity protocol employed in the study has previously been shown to be sensitive to treatment effects as well as have good construct and discriminant validity (Keefe & Block, 1982), future studies may want to employ additional simulations of activities in order to assess pain behaviors. For example, Weiner, Pieper, McConnell, Martinez, & Keefe (1996) found that an 'ADL protocol' consisting of standardized tasks that place a premium on axial movement (i.e. bridging, lying prone, supine to sit, and long leg sit) elicited a higher frequency of pain behaviors than did the 'traditional protocol' employed in the present study.

Future studies should also include measures of social engagement and quality of life as these domains may also shed more light on the ways in which persons with dementia express pain as well as how they benefit from pain treatment. It may also be beneficial to exclude persons taking psychotropic medications in order to assess the relationship between chronic pain and excess disabilities. However, this may not be reasonable, as many persons with dementia are prescribed these medication; for example 4 of the 5 persons with dementia that were enrolled in this study were taking at least one antipsychotic medication.

Also, this longitudinal study extends prior research findings that were cross-sectional in nature, providing evidence that over time, pain behavior, including the severity of excess disabilities, is responsive to treatment, and that caregivers are capable of reliably assessing pain and the effectiveness of a pain intervention. Also, future studies should aim to increase caregiver training on the study measures in order to further ensure that caregivers are capable of using the measurement tools and providing reliable assessments. Additionally, it may be of benefit for future studies to examine the intra-individual variability of pain over time, because although chronic pain is persistent in nature, it is not necessarily constant, and often fluctuates, even over the course of a day (Keefe, 1995; Werner et al., 1998). These fluctuations and their effect on pain assessment have not been fully explored in the literature.

In future studies it may be worthwhile to investigate alternate tool choices for use with caregivers to detect a change in excess disabilities in response to pain relief. Chinball and colleagues (2005) found utility in using the Dementia Care Mapping tool to show that scheduled doses of acetaminophen did positively affect participants' behavior, facilitating increased engagement with their environment. Herr and colleagues (2006) rated the discomfort in dementia of the Alzheimer's type (DS-DAT) tool the highest after evaluating 10 pain assessment tools. However, the authors caution that although the measure has been used to assess pain in older adults with dementia, because its focus is discomfort and it does not address pain-related indicators identified in recent literature. Additionally, Shah and colleagues (2004) used the BEHAVE-AD tool to measure excess disabilities and found that scores on this measure were negatively correlated with MMSE scores, indicating that the severity of excess disabilities increased as cognition decreased.

Furthermore, several researchers have found the Facial Action Coding System to useful in detecting pain in non-verbal populations (Hadjistavropoulos et al., 1998; Porter et al., 1996). Finally, the Pain Assessment in Advanced Dementia (PAINAD) scale has shown good construct validity as it was able to detect differences in pain after analgesic administration (Warden et al., 2003).

The next step for any of these measures is to validate their ability to accurately assess pain in the community-dwelling population of older adults with dementia. After all, the majority of older adults with dementia reside in the community with either family or paid caregivers and yet no pain assessment tool exists for use in this population. Most researchers have thought that this group of elders is more mildly or moderately cognitively impaired and thus may be capable of self-reporting pain. However, each of the 5 subjects recruited to participate in the present study were severely cognitively impaired, and while some maintained verbal abilities, none of the caregivers considered their self-report reliable. As advances have been made in the field of health care for older adults with dementia, and community-based support programs have grown, a greater number of older adults with dementia are residing at home longer, into the severe stages of cognitive impairment. Therefore, this group of persons with dementia, and especially their caregivers, are in need of useful and valid pain assessment and treatment strategies. The present study is first step towards identifying an intervention that is useful in treating chronic osteoarthritic pain in community-dwelling older adults with dementia. If measurement tools are refined to help caregivers accurately assess chronic pain and the effects of pain interventions in the community-dwelling population with dementia,

caregivers would be greatly aided in their daily comfort and care of their loved ones, who they continue to care for at home.

APPENDIX A
PERFORMING GRAPHICAL ANALYSES FOR SINGLE-SUBJECT DESIGN DATA

Example 1: Determining changes in the mean for each phase

Table A-1 Calculating the Mean

	Phase A1 (N=8)	Phase B1 (N=8)	Phase A2 (N=4)	Phase B2 (N=4)
Daily values	41	21	20	23
	34	20	24	17
	30	14	28	16
	36	17	38	14
	33	24		
	25	14		
	26	18		
	32	21		
Total	257	149	110	70
Mean (Total/N)	32.13	18.63	27.5	17.5

In order to interpret whether the mean changes support the effectiveness of the intervention, the mean for the behavior of interest should be higher in the baseline phases (if the behavior is unwanted, such as pain behavior) and lower during the intervention phases (when the intervention's goal is to reduce the behavior of interest).

Example 2: Determining the latency of change between study phases

The latency of change (i.e. the period between the onset or termination of one phase and subsequent changes in behavior) is determined by assessing both the change in level between phases and the change in trend (slope) between phases.

Next, a dashed line can be placed on the graph representing the mean for each phase:

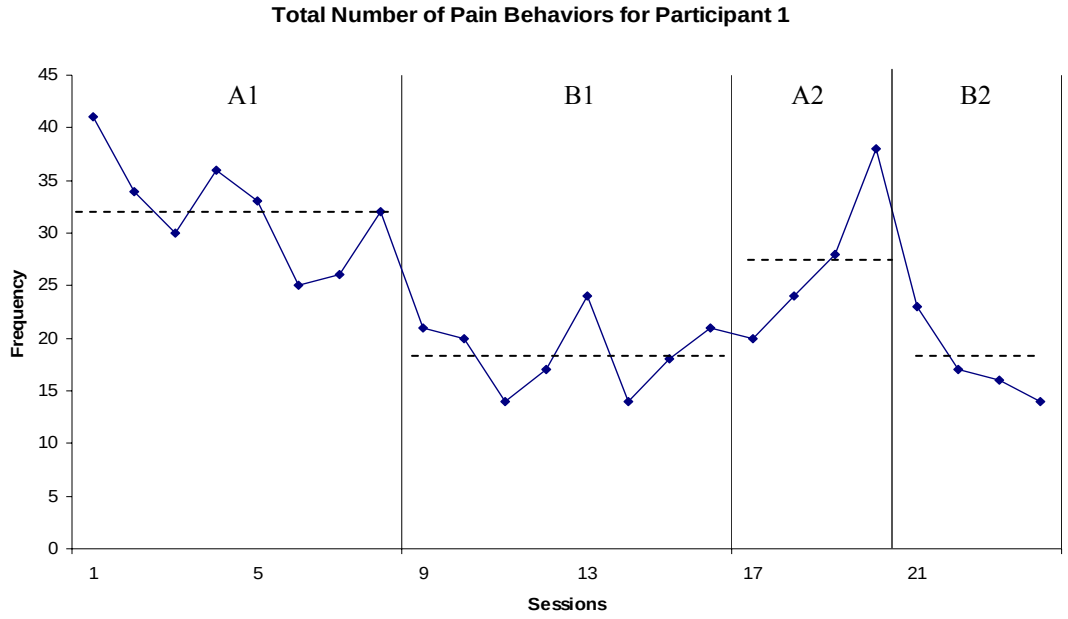


Figure A-1. Presenting the mean for each phase in the graph.

Table A-2 Calculating the Level Change between Phases

	A1 to B1	B1 to A2	A2 to B2
Last value in first phase	32	21	38
First value in next phase	21	20	23
Difference (last value of the first phase – first value of next phase)	11 point decrease*	1 point decrease*	15 point decrease*

* If the first value of the next phase is smaller than the last value of the first phase, then there is a decrease in level between phases. If it is larger than the preceding value, then there is an increase in level between phases.

Next, the trend (slope) for each phase can be calculated in Excel after graphing the data points for one phase. When these data points are selected, Excel will draw a trendline and there is an option to display the equation of this trend line on the graph. (See Figure A2). For interpreting the latency of change, the magnitude of the level change and slope change are examined together. The first aspect to evaluate is whether or not the change was in the intended direction. For instance, when the aim of the

intervention is to produce a decrease in the target behavior, there should be a decrease in level when going from a baseline phase into an intervention phase and an increase in level when transitioning from an intervention phase into a baseline phase. Also, the trend in the baseline phase should be in the positive (increasing) direction and in the negative (decreasing) direction during the intervention phases.

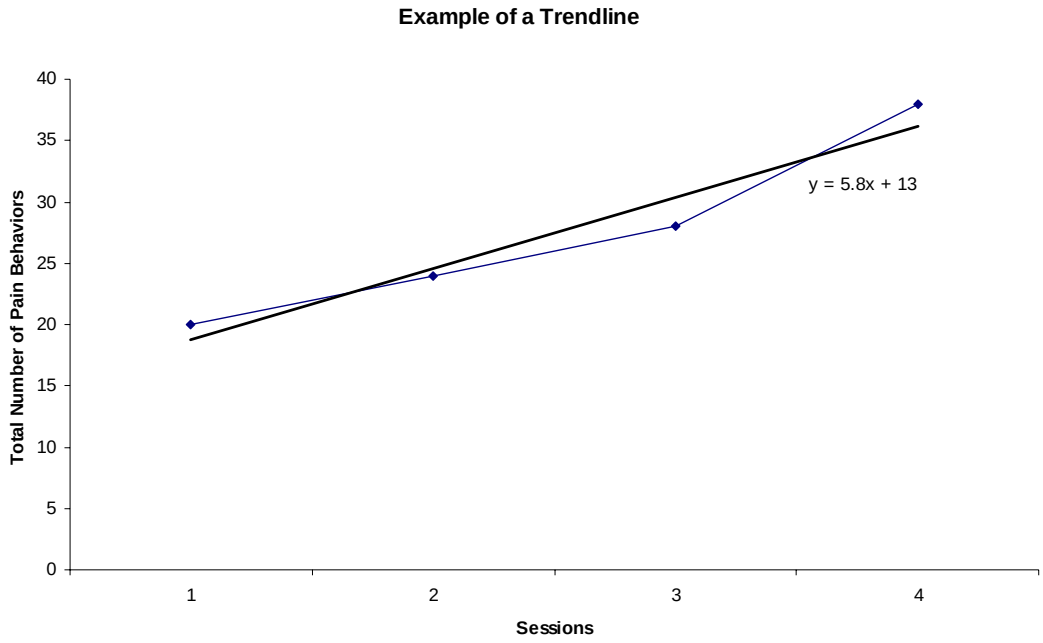


Figure A-2. Example of a trendline produced in Excel.

The next aspect to consider is the rapidity of change between phases. A short period of latency (quick change in behavior) strengthens the findings that the intervention was very effective in producing the observed change in behavior. Short latency periods are represented by large level and trend changes in the intended directions. Slower periods of latency are characterized by smaller level and slope changes in the intended directions. If changes in either level or trend are in the unintended directions, there are

conflicting results. When results are conflicting, there is less support for the intervention's effectiveness.

Table A-3 Determining the Latency of Change between Phases

	Level Change	Trend Change	Latency
Phase A1 to B1	11 point decrease (intended direction)	-1.4 to -.04 (initially slope is in the unintended direction and flattens in the intervention phase)	Conflicting pattern of change
Phase B1 to A2	1 point decrease (unintended direction)	-.04 to 5.8 (change is in the intended direction)	Slow latency of change
Phase A2 to B2	15 point decrease (intended direction)	5.8 to -2.8 (change is in the intended direction)	Quick period of latency

Example 3: Determining overlap of the data between phases

Overlap of data between phases is determined simply by looking at the number of data points in each phase that are within the range of data points from the adjacent phases. For example, looking at Table A1, the range of data points in phase A1 was 25 to 41, in phase B1 the range was 14 to 24. Thus, there was no overlap of data between phases A1 and B1. Support for the effectiveness of the intervention is strengthened when there is little to no overlap of data between phases. When there is a lot of overlap, it may be that the latency of change was slow, or that the intervention was not very effective.

Example 4: Determining the stability of data within phases

The stability of data within phases is determined by calculating the number of data points in a phase that fall within a range 15% above to 15% below the trendline for the phase. In the present study, this was calculated by first finding 15% of the mean for a particular phase. This value was then added and subtracted from each individual data point in order to establish a set of values that would have the same trendline as the original data set but would represent a range both 15% above and 15% below the original

data. Next, all three data sets were graphed in excel, and the trendline for each of the three lines were added. Finally, the percentage of original data points falling within the range represented by the 15% higher and 15% lower trendlines was calculated and served as the measure of stability of data within each phase. (See Table A3 and Figure A3 for an illustration of this procedure).

Table A-4 Calculating 15% Above and 15% Below the Mean

Original Data Point (Mean= 27.5; 15% of mean= 4.125)	15% Above (Original data point + 4.125)	15% Below (Original data point – 4.125)
20	24.125	15.875
24	28.125	19.875
28	32.125	23.875
38	42.125	33.875

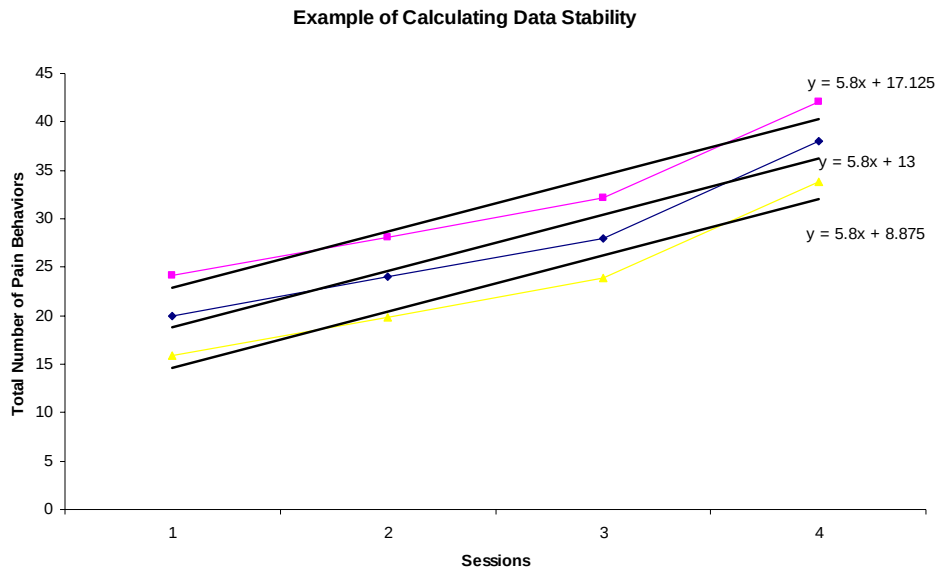


Figure A-3. Example of calculating the stability of data points within a study phase.

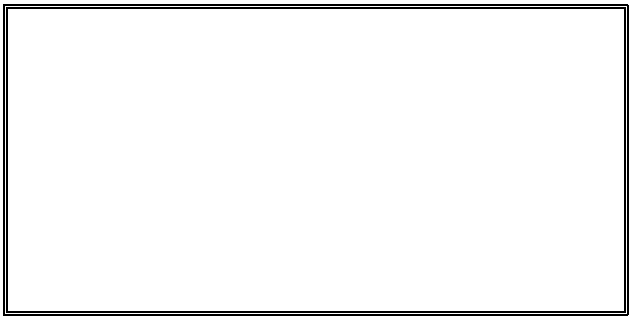
As can be seen in Figure A3, all of the points from the original data set (blue line) fall within a range of 15% above and 15% below the original trendline. Thus, the data in

this example reached 100% stability. Usually, stability within a phase strengthens the argument that the intervention produced the desired effect, rather than an extraneous variable. However, in the present study, the behaviors of interest (pain and excess disabilities) were thought to be variable in nature, so there was not a high expectation for stability of data within baseline phases.

APPENDIX B
INFORMED CONSENT TO PARTICIPATE IN RESEARCH-CHRONIC PAIN PARTICIPANT

IRB# 069-2005

Informed Consent to Participate in Research and Authorization for Collection, Use, and Disclosure of Protected Health Information



You are being asked to take part in a research study. This form provides you with information about the study and seeks your authorization for the collection, use and disclosure of your protected health information necessary for the study. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits to which you would otherwise be entitled.

1. Name of Participant ("Study Subject")- Person with Chronic Pain

_____

2. Title of Research Study

Assessing and Treating Chronic Pain in Community-Dwelling Older Adults with Dementia: A Single-Subject Approach

3. Principal Investigator and Telephone Number(s)

Amanda Floetke Elliott, PhDc, ARNP Doctoral Candidate
University of Florida College of Nursing
Phone (352) 216-4165

4. Source of Funding or Other Material Support

John A. Hartford Foundation Building Academic Geriatric Nursing Capacity Predoctoral Scholarship

5. What is the purpose of this research study?

You are being asked to participate in a research study about chronic pain in older adults with memory problems. We would like to learn more about effective ways to treat your pain. We will do this by asking you to take Tylenol Arthritis medication and allowing us to observe your behavior. As part of the research, we are asking you to a) participate in an interview during which the principal investigator will ask you to complete a series of questionnaires and surveys, b) to take the medication Tylenol Arthritis, and c) to complete a series of physical tasks. These tasks are things that you would do on a normal daily basis such as walking, sitting, standing, and reclining in bed.

6. What will be done if you take part in this research study?

Once you have agreed to participate in this study, you will be interviewed in your home and will complete some tests to assess your thinking abilities. You will then be asked to complete some physical activities. During these activities, you will be videotaped. There is an additional form to consent to videotaping at the end of this Informed Consent Form. In addition, your caregiver will be asked questions about your health. There will be 4 total study phases each lasting approximately 8 sessions (one session per day). In 2 of these phases you will also be asked to take the medication Tylenol Arthritis by mouth every 8 hours that you are awake. The entire study will take place in your home.

If you have any questions now or at any time during the study, you may contact the Principal Investigator listed in #3 of this form.

7. If you choose to participate in this study, how long will you be expected to participate in the research?

The study is scheduled to last approximately 30 to 45 days during which the Principal Investigator will be visiting you between 24 to 40 times. Each session will last approximately one hour.

8. How many people are expected to participate in this research?

Up to six person-caregiver dyads, including you, are expected to participate in this research study.

9. What are the possible discomforts and risks?

There are no anticipated risks associated with this study. However, this study may include risks that are unknown at this time. There may be a slight risk from taking the medication Tylenol Arthritis. While this drug has a very low side-effect profile you should not take it if you have impaired kidney or liver function or a known allergy to acetaminophen.

By participating in this study, there is a slight physical risk of falling or having a physical injury while you do the physical activities. This risk is no greater than what you would experience every day because the activities you will be asked to do are things you normally do, such as sitting, walking, standing, and lying in bed. There will be trained personnel and/or a registered nurse present during the activities to minimize any potential physical risk.

There is also a slight emotional risk due to being asked questions about your thinking abilities and your pain. This might include feeling sad, depressed, or anxious about your pain and/or your physical and thinking abilities. If you experience this distress, you are free to refuse to answer any questions, refuse to participate in the upsetting activity, or drop out of the study. After your interviews are complete, you will have an opportunity to discuss your feelings with the Principal Investigator. Should the results of the depression questionnaire indicate that you might have a problem with depression, you will be provided with a list of healthcare professionals to help you with this problem.

There are no social risks associated with this study; that is, you are in no public or social danger as a result of this study. The only possible risk of this type would involve embarrassment to you if other people found out personal information about your pain. In order to minimize this risk, you will be identified only by a code number, and your information will never be matched to your name.

Participation in more than one research study or project may further increase the risks to you. Please inform the Principal Investigator (listed in #3 of this consent form) or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, you may ask questions now or call the Principal Investigator or contact person listed on the front page of this form.

10a. What are the possible benefits to you?

You may personally benefit from participating in this study by experiencing a relief in your chronic pain. You may also benefit from the opportunity to talk about your pain.

10b. What are the possible benefits to others?

The results of this study may provide important information about the treating chronic pain in older adults with memory problems.

11. If you choose to take part in this research study, will it cost you anything?

There is no cost to you. You may participate in the study at no charge.

12. Will you receive compensation for taking part in this research study?

You will receive compensation for taking part in this research study. The Tylenol Arthritis medication will be given to you and you will receive $50 for completion of each study phase. There are a total of 4 study phases so you could receive a total of $200 for your participation in this study.

If you are paid for taking part in this study, your name and social security number will be reported to University administrative personnel for purposes of making and recording the payment.

13. What if you are injured because of the study?

If you experience an injury that is directly caused by this study, only professional consultative care that you receive at the University of Florida Health Science Center will be provided without charge. However, hospital expenses will have to be paid by you or your insurance provider. No other compensation is offered. Please contact the Principal Investigator listed in Item 3 of this form if you experience an injury or have any questions about any discomforts that you experience while participating in this study.

14. What other options or treatments are available if you do not want to be in this study?

Participation in this study is entirely voluntary. You are free to refuse to be in this study, and your refusal will not influence current or future health care you receive at the University of Florida Health Science Center. The treatment medicine given in

this study is available over the counter and you do not have to participate in this study to obtain this medication.

15a. Can you withdraw from this research study?

You are free to withdraw your consent and to stop participating in this research study at any time. If you do withdraw your consent, there will be no penalty, and you will not lose any benefits you are entitled to.

If you decide to withdraw your consent to participate in this research study for any reason, you should contact Amanda Floetke Elliott at (352) 216-4165.

If you have any questions regarding your rights as a research subject, you may phone the Institutional Review Board (IRB) office at (352) 846-1494.

15b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this research study, no further information about you will be collected. However, with your permission, we would like to use the information that has been collected until the date you withdrew from the study.

15c. Can the Principal Investigator withdraw you from this research study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information about this.
- The study treatments have a bad effect on you.
- You are unable to keep appointments or take study drugs as directed.

16. If you agree to participate in this research study, the Principal Investigator will create, collect, and use private information about you and your health. Once this information is collected, how will it be kept secret (confidential) in order to protect your privacy?

Information collected about you and your health (called protected health information), will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not

be released without your permission unless required by law or a court order.
If you participate in this research study, the researchers will collect, use, and share your protected health information with others. Items 17 to 26 below describe how this information will be collected, used, and shared.

17. If you agree to participate in this research study, what protected health information about you may be collected, used and shared with others?

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Complete past medical history to determine if you meet eligibility criteria
- Records of physical exams and medical diagnoses
- Diaries and questionnaires
- Records about medications
- Memory tests

If you agree to be in this research study, it is possible that some of the information collected might be copied into a "limited data set" to be used for other research purposes. If so, the limited data set may only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, numbers, codes, or so forth that link you to the information in the limited data set. If used, limited data sets have legal agreements to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your protected health information may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your protected health information may be collected, used, and shared with others for the following study-related purpose(s):

- To determine the effectiveness of the study drug in treating your chronic pain.

19. Who will be allowed to collect, use, and share your protected health information?

Your protected health information may be collected, used, and shared with others by:

- the study Principal Investigator Amanda Floetke Elliott and her staff
- your caregiver
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures
- the University of Florida Institutional Review Board

20. Once collected or used, who may your protected health information be shared with?

Your protected health information may be shared with:

- the study sponsor the John A. Hartford Foundation Building Academic Geriatric Nursing Capacity Scholars Program
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and Federal, State and local health departments

21. If you agree to participate in this research, how long will your protected health information be used and shared with others?

Your protected health information will be collected, used, and shared until the end of the study.

22. Why are you being asked to allow the collection, use and sharing of your protected health information?

Under a new Federal Law, researchers cannot collect, use, or share with others any of your protected health information for research unless you allow them to by signing this consent and authorization.

23. Are you required to sign this consent and authorization and allow the researchers to collect, use and share with others your protected health information?

No, and your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. *However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent/authorization.*

24. Can you review or copy your protected health information that has been collected, used or shared with others under this authorization?

You have the right to review and copy your protected health information. However, you will not be allowed to do so until after the study is finished.

25. Is there a risk that your protected health information could be given to others beyond your authorization?

Yes. There is a risk that information received by authorized persons could be given to others beyond your authorization and not covered by the law.

26. Can you revoke (cancel) your authorization for collection, use and sharing with others of your protected health information?

Yes. You can revoke your authorization at any time before, during, or after your participation in the research. If you revoke, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete and protect the validity of the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

27. How will the researcher(s) benefit from your being in this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals.

28. Signatures

As a representative of this study, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____

Signature of Person Obtaining Consent & Authorization Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-26 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____

Consent & Authorization Signature of Parent/Legal Representative — Date

_____

Print: Name of Legal Representative of and Relationship to Participant:

Relationship to Participant:

___ Health care surrogate
___ Power of attorney
___ Guardian
___ Spouse
___ Adult child
___ Adult sibling
___ Adult relative

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____

Assent Signature of Participant Date

Consent to be Videotaped and to Different Uses of the Videotape(s)

With your permission, you will be videotaped during this research. Your name or personal information will not be recorded on the videotape, and confidentiality will be strictly maintained. When these videotapes are shown, however, others may be able to recognize you.

The Principal Investigator of this study, Amanda Floetke Elliott, or her successor, will keep the videotape(s) in a locked cabinet. These videotapes will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please sign ***one*** of the following statements that indicates under what conditions Ms. Elliott has your permission to use the videotape.

I give my permission to be videotaped solely for this research project under the conditions described.

_____Signature _____Date

I give my permission to be videotaped for this research project, as described in the Informed Consent Form, and for the purposes of education at the University of Florida Health Science Center

_____Signature _____Date

I give my permission to be videotaped for this research project, as described in the Informed Consent Form; for the purposes of education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University.

_____Signature _____Date

APPENDIX C
INFORMED CONSENT TO PARTICIPATE IN RESEARCH-CAREGIVERS

IRB# 069-2005

Informed Consent to Participate in Research and Authorization for Collection, Use, and Disclosure of Protected Health Information

You are being asked to take part in a research study. This form provides you with information about the study and seeks your authorization for the collection, use and disclosure of your protected health information necessary for the study. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits to which you would otherwise be entitled.

1. Name of Participant ("Study Subject")

_____

2. Title of Research Study

Assessing and Treating Chronic Pain in Community-Dwelling Older Adults with Dementia: A Single-Subject Approach

3. Principal Investigator and Telephone Number(s)

Amanda Floetke Elliott, PhDc, ARNP Doctoral Candidate
University of Florida College of Nursing
Phone (352) 216-4165

4. Source of Funding or Other Material Support

John A. Hartford Foundation Building Academic Geriatric Nursing Capacity Predoctoral Scholarship

5. What is the purpose of this research study?

You are being asked to participate in a research study about chronic pain in older adults with memory problems. We would like to learn more about effective ways to treat your loved one's pain. We will do this by asking you to give your loved one Tylenol Arthritis medication and allowing us to observe their behavior. As part of the research, we are asking you to a) participate in an interview during which the Principal Investigator will ask you to complete a series of questionnaires and surveys, b) to give the medication Tylenol Arthritis to your loved one, and c) to complete daily measures of your loved one's behavior. In addition we are asking your loved one to perform a series of tasks that we will videotape. There is an additional form to consent to videotaping at the end of your loved one's Informed Consent Form. These tasks are things that they would do on a normal daily basis such as walking, sitting, standing, and reclining in bed.

6. What will be done if you take part in this research study?

Once you have agreed to participate in this study, you will be interviewed in your home and will complete some tests to assess your thinking abilities. You will then be asked to learn 2 measures to rate your loved one's behavior. The Principal Investigator will work with you to help you use these measures reliably. There will be 4 total study phases each lasting approximately 8 sessions (one session per day). In 2 of these phases you will also be asked to give your loved one the medication Tylenol Arthritis by mouth every 8 hours that he/she is awake. The entire study will take place in your home.

If you have any questions now or at any time during the study, you may contact the Principal Investigator listed in #3 of this form.

7. If you choose to participate in this study, how long will you be expected to participate in the research?

The study is scheduled to last approximately 30 to 45 days during which the Principal Investigator will be visiting you between 24 to 40 times. Each session will last approximately one hour.

8. How many people are expected to participate in this research?

Up to six person-caregiver dyads, including you, are expected to participate in this research study.

9. What are the possible discomforts and risks?

There are no anticipated risks associated with this study. However, this study may include risks that are unknown at this time. There may be a slight risk to your loved one from taking the medication Tylenol Arthritis. While this drug has a very low side-effect profile, persons who have impaired kidney or liver function or a known allergy to acetaminophen should not take this drug.

There are no physical risks for you. However, there is a slight physical risk for your loved one of falling or having a physical injury while he/she performs the physical activities. This risk is no greater than what someone would experience every day because the activities include things people normally do, such as sitting, walking, standing, and lying in bed. There will be trained personnel and/or a registered nurse present during the activities to minimize any potential physical risk.

There is a slight emotional risk due to being asked questions about your thinking abilities and your loved one's behavior. This might include feeling sad, depressed, or anxious about your thinking abilities or your loved one's behavior. If you experience this distress, you are free to refuse to answer any questions, refuse to participate in the upsetting activity, or drop out of the study. After your interviews are complete, you will have an opportunity to discuss your feelings with the Principal Investigator. Should the results of the depression questionnaire indicate that you might have a problem with depression, you will be provided with a list of healthcare professionals to help you with this problem.

There are no social risks associated with this study; that is, you are in no public or social danger as a result of this study. The only possible risk of this type would involve embarrassment to you if other people found out personal information about you or your loved one. In order to minimize this risk, you and your loved one will be identified only by a code number, and your information will never be matched to your name.

Participation in more than one research study or project may further increase the risks to you. Please inform the Principal Investigator (listed in #3 of this consent form) or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, you may ask questions now or call the Principal Investigator or contact person listed on the front page of this form.

10a. What are the possible benefits to you?

You may personally benefit from participating in this study by gaining an understanding of how to assess your loved one's pain. You may also benefit from decreased stress and burden if your loved one's behavior improves.

10b. What are the possible benefits to others?

The results of this study may provide important information about the treating chronic pain in older adults with memory problems.

11. If you choose to take part in this research study, will it cost you anything?

There is no cost to you. You may participate in the study at no charge.

12. Will you receive compensation for taking part in this research study?

You will receive compensation for taking part in this research study. The Tylenol Arthritis medication will be given to you and you will receive $50 for the completion of each study phase. There are a total of 4 study phases, so you could receive a total of $200 for your participation in this study.

If you are paid for taking part in this study, your name and social security number will be reported to University administrative personnel for purposes of making and recording the payment.

13. What if you are injured because of the study?

If you experience an injury that is directly caused by this study, only professional consultative care that you receive at the University of Florida Health Science Center will be provided without charge. However, hospital expenses will have to be paid by you or your insurance provider. No other compensation is offered. Please contact the Principal Investigator listed in Item 3 of this form if you experience an injury or have any questions about any discomforts that you experience while participating in this study.

14. What other options or treatments are available if you do not want to be in this study?

Participation in this study is entirely voluntary. You are free to refuse to be in this study, and your refusal will not influence current or future health care you receive at the University of Florida Health Science Center. The treatment medicine given in

this study is available over the counter and you do not have to participate in this study to obtain this medication.

15a. Can you withdraw from this research study?

You are free to withdraw your consent and to stop participating in this research study at any time. If you do withdraw your consent, there will be no penalty, and you will not lose any benefits you are entitled to.

If you decide to withdraw your consent to participate in this research study for any reason, you should contact Amanda Floetke Elliott at (352) 216-4165.

If you have any questions regarding your rights as a research subject, you may phone the Institutional Review Board (IRB) office at (352) 846-1494.

15b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this research study, no further information about you will be collected. However, with your permission, we would like to use the information that has been collected until the date you withdrew from the study.

15c. Can the Principal Investigator withdraw you from this research study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not qualify to be in the study because you do not meet the study requirements. Ask the Principal Investigator if you would like more information about this.
- The study treatments have a bad effect on your loved one.
- You are unable to keep appointments or give study drugs as directed.

16. If you agree to participate in this research study, the Principal Investigator will create, collect, and use private information about you and your health. Once this information is collected, how will it be kept secret (confidential) in order to protect your privacy?

Information collected about you and your health (called protected health information), will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not

be released without your permission unless required by law or a court order.

If you participate in this research study, the researchers will collect, use, and share your protected health information with others. Items 17 to 26 below describe how this information will be collected, used, and shared.

17. If you agree to participate in this research study, what protected health information about you may be collected, used and shared with others?

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Diaries and questionnaires
- Memory tests

If you agree to be in this research study, it is possible that some of the information collected might be copied into a "limited data set" to be used for other research purposes. If so, the limited data set may only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, numbers, codes, or so forth that link you to the information in the limited data set. If used, limited data sets have legal agreements to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your protected health information may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your protected health information may be collected, used, and shared with others for the following study-related purpose(s):

- To determine the effectiveness of the study drug in treating your loved one’s chronic pain.

19. Who will be allowed to collect, use, and share your protected health information?

Your protected health information may be collected, used, and shared with others by:

- the study Principal Investigator Amanda Floetke Elliott and her staff
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures
- the University of Florida Institutional Review Board

20. Once collected or used, who may your protected health information be shared with?

Your protected health information may be shared with:

- the study sponsor the John A. Hartford Foundation Building Academic Geriatric Nursing Capacity Scholars Program
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and Federal, State and local health departments

21. If you agree to participate in this research, how long will your protected health information be used and shared with others?

Your protected health information will be collected, used, and shared until the end of the study.

22. Why are you being asked to allow the collection, use and sharing of your protected health information?

Under a new Federal Law, researchers cannot collect, use, or share with others any of your protected health information for research unless you allow them to by signing this consent and authorization.

23. Are you required to sign this consent and authorization and allow the researchers to collect, use and share with others your protected health information?

No, and your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. *However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent/authorization.*

24. Can you review or copy your protected health information that has been collected, used or shared with others under this authorization?

You have the right to review and copy your protected health information. However, you will not be allowed to do so until after the study is finished.

25. Is there a risk that your protected health information could be given to others beyond your authorization?

Yes. There is a risk that information received by authorized persons could be given to others beyond your authorization and not covered by the law.

26. Can you revoke (cancel) your authorization for collection, use and sharing with others of your protected health information?

Yes. You can revoke your authorization at any time before, during, or after your participation in the research. If you revoke, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete and protect the validity of the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

27. How will the researcher(s) benefit from your being in this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals.

28. Signatures

As a representative of this study, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-26 above. By signing this form, you are not waiving any of your legal rights.

_____

Signature of Person Consenting and Authorizing Date

APPENDIX D
DAILY CAREGIVER QUESTIONNAIRES

ID # _____

Caregiver's View of the Participant

THIS INFORMATION IS CONFIDENTIAL AND WILL NOT BE USED FOR ANY KIND OF EVALUATION OF THE WAY YOU TAKE OF THE PARTICIPANT

I. PADE (Pain Assessment in the Dementing Elderly)

INSTRUCTIONS

Please take five minutes or so to unobtrusively observe the participant's behavior, and then answer the following questions based on your observations. For each question, place a vertical slash mark on the line.

1. Does the participant have a "sad" facial expression? None----------extreme
2. Does the participant have an "anxious/frightened" facial expression? None----------extreme
3. Is the participant frowning? Not frowning----------continuously
4. Is the participant displaying "tense" body language? None----------continuously
5. Is the participant restless? Calm----------extremely restless
6. During transfers, does the participant grimace, brace him/herself, groan, etc.? None----------extreme
7. Does the participant reach for or guard the affected area? (e.g., source of arthritic pain) None----------extreme

For questions 8-10, if the participant is silent during your period of observation, circle Not Applicable below and skip to question 11.

NOT APPLICABLE

8. Is the participant moaning/groaning?	None----------continuously
9. Does the participant's speech or other vocalizations sound distressed?	Not distressed----------highly distressed
10. How coherent and complex was the participant's language?	Completely fluent ----------No No problems noted recognizable language used
11. Does breathing sound loud, gasping, etc.?	Normal----------extremely abnormal
12. Is the participant breathing rapidly or hyperventilating?	Normal----------hyperventilating
13. How neatly/appropriately groomed is the participant at the time of your observation?	1= very neat/appropriately groomed; e.g., clothing, hair, make-up, shaving, etc. 2= clothing appropriate, but not "perfect" (e.g., wearing only one shoe, shirt not buttoned correctly, etc.); grooming should be adequate (e.g., hair combed even if not "perfect," make-up applied well but maybe a bit heavy, etc.) 3= more problems with hair, clothing, make-up, shaving, etc., noted, but it is obvious that an attempt was made to be appropriate 4= disheveled, not wearing appropriate clothing (e.g., hair uncombed, still in pajamas in the afternoon, etc)
14. Please place a mark on the line that <u>you</u> feel best represents the participant's level of pain at the time of observation.	None----------severe

Please answer the following questions based on THE PAST 24 HOURS, unless otherwise indicated.

15. How independent was the participant in eating his/her most recent meal?	1= independent 2= supervision 3= limited 4= extensive/total
16. What was the average amount eaten of the last three meals?	1= all 2= ¾ 3= ½

	4= ¼ or less
17. Out of the last three meals that the participant ate, how many were in his/her bed room as opposed to their usual dining location?	1= all in usual dining location 2= one in room 3=two in room 4= all in room
18. What percentage of the last 24 hours has the participant been awake? (If the participant has been awake for 24 hours, please circle Not Applicable)	1= 75-100% 2= 50-74% 3= 25-49% 4= <25%
NOT APPLICABLE	
19. During the hours that the participant has been awake, what percentage of time was the participant out of bed?	1= 75-100% 2= 50-74% 3= 25-49% 4= <25%
20. During the hours that the participant has been awake, what percentage of the time was spent out of his/her room interacting with others? (e.g., participating in a planned activity, watching TV with others, etc.	1= 75-100% 2= 50-74% 3= 25-49% 4= <25%
21. How cooperative has the participant been during any needed assists? (e.g., getting dressed, eating meals, etc.) Please circle Not Applicable if the participant is fully independent in ADLs.)	1= fully cooperative 2= completed with minimal encouragement 3= completed with moderate encouragement 4= activity unable to be completed
NOT APPLICABLE	
22. What level of agitation has the participant displayed during the past 24 hours?	1= none 2= vocal expression, etc., brought under control with single redirection 3= vocal expression, etc., not brought under control or physical striking out brought under control with one to one attention 4= required PRN/psycho-active meds or restraint
23. How much is the participant wandering/pacing/fidgety?	None----------participant rarely sitting; constantly moving
24. How much is the participant indicating that he/she wants to leave the residence?	None----------constantly indicating

II. RMBPC (The Revised Memory and Behavior Problems Checklist)

INSTRUCTIONS

The following is a list of problems individuals sometimes have. Please tell us if any of these problems have occurred during the past 24 hours. If so, how much has this bothered or upset you when it happened? Use the following scales for the frequency of the problem and your reaction to it. Please read the description of the ratings carefully.

	How Often? 0= never occurred 1= not in the past 24 hours 2= 1-2 times 3= 3-6 times 4= >6 times 9= don't know/ not applicable	How Disturbing? 0= not al all 1= a little 2= moderately 3= very much 4= extremely 9= don't know/ not applicable
1. Asking the same question over and over again,	0 1 2 3 4 9	0 1 2 3 4 9
2. Trouble remembering recent events (e.g., items in the newspaper or on TV).	0 1 2 3 4 9	0 1 2 3 4 9
3. Trouble remembering significant past events.	0 1 2 3 4 9	0 1 2 3 4 9
4. Losing or misplacing things.	0 1 2 3 4 9	0 1 2 3 4 9
5. Forgetting what day it is.	0 1 2 3 4 9	0 1 2 3 4 9
6. Starting, but not finishing, things.	0 1 2 3 4 9	0 1 2 3 4 9
7. Difficulty concentrating on a task.	0 1 2 3 4 9	0 1 2 3 4 9
8. Destroying property.	0 1 2 3 4 9	0 1 2 3 4 9
9. Doing things that embarrass you.	0 1 2 3 4 9	0 1 2 3 4 9
10. Waking you or other family members up at night	0 1 2 3 4 9	0 1 2 3 4 9
11. Talking loudly and rapidly.	0 1 2 3 4 9	0 1 2 3 4 9
12. Appears anxious or worried.	0 1 2 3 4 9	0 1 2 3 4 9
13. Engaging in behavior that is potentially dangerous to self or others.	0 1 2 3 4 9	0 1 2 3 4 9

14. Threats to hurt oneself.	0	1	2	3	4	9	0	1	2	3	4	9
15. Threats to hurt others.	0	1	2	3	4	9	0	1	2	3	4	9
16. Aggressive to others verbally.	0	1	2	3	4	9	0	1	2	3	4	9
17. Appears sad or depressed.	0	1	2	3	4	9	0	1	2	3	4	9
18. Expressing feelings of hopelessness or sadness about the future (e.g., "Nothing worthwhile ever happens," "I never do anything right").	0	1	2	3	4	9	0	1	2	3	4	9
19. Crying and tearfulness.	0	1	2	3	4	9	0	1	2	3	4	9
20. Commenting about death of self or others (e.g., "Life isn't worth living," "I'd be better off dead").	0	1	2	3	4	9	0	1	2	3	4	9
21. Talking about feeling lonely.	0	1	2	3	4	9	0	1	2	3	4	9
22. Comments about feeling worthless or being a burden to others.	0	1	2	3	4	9	0	1	2	3	4	9
23. Comments about feeling like a failure or about not having any worthwhile accomplishments in life.	0	1	2	3	4	9	0	1	2	3	4	9
24. Arguing, irritability, and/or complaining.	0	1	2	3	4	9	0	1	2	3	4	9

III. Caregiver Questionnaire

1. How typical was today compared to most days? (i.e. where there any doctor's appointments, visitors, etc.)

2. What behaviors did you notice that were most representative of pain in the participant today? (Please include anything that signaled pain to you, even if it was not part of the other two questionnaires).

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BIOGRAPHICAL SKETCH

Amanda Floetke Elliott was born in Detroit, Michigan, to Karl and Nancy Floetke. She was raised in Seminole, Florida, after the age of 7. Amanda graduated from the International Baccalaureate Program at St. Petersburg High School in 1997. Amanda obtained her Bachelor of Science degree in nursing from the University of Florida in 2001. She then entered the University of Florida College of Nursing's BSN-to-PhD program in the fall of 2001. Amanda received her master's in nursing as an Adult Health Advance Registered Nurse Practitioner in 2002. Amanda has worked as a circulating nurse in the Operating Room at Shands Hospital at the University of Florida (2001-2002) and as a Research Assistant for Dr. Ann Horgas (2000-2005) and Dr.Meredeth Rowe (2004). As a graduate student Amanda received the University of Florida Alumni Association Fellowship, the John A. Hartford Building Academic Geriatric Nursing Capacity Predoctoral Scholarship, and a T32 Training Program in Aging Scholarship from the University of Florida. Her interests include pain assessment and treatment in older adults with dementia, as well as the role of informal caregivers for older adults with dementia. Upon completion of her doctoral degree, Amanda plans to pursue a post-doctoral fellowship in aging.