

The Assessment of Good Practice in Pain  
Management in Severe Dementia: a Pilot Study

By

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## **Abstract**

### THE ASSESSMENT OF GOOD PRACTICE IN PAIN MANAGEMENT IN SEVERE DEMENTIA: A PILOT STUDY

**Introduction:** Dementia constitutes a major problem for sufferers, carers and society as a whole. In common with other progressive life threatening conditions, it has been increasingly recognised that the principles of palliative care should apply to patients with dementia [1]. One important aspect of care is management of pain, which may contribute to agitated behaviour in dementia. Studies suggest that pain is under-recognised and under-treated in those with severe dementia [2]. Identifying pain is the first step in its effective management. However, research has not been carried out in the UK regarding the utility of behavioural pain and distress assessment tools in those with advanced dementia. The aim of the research was to demonstrate the importance of assessing and managing pain as part of good quality palliative care in people with severe dementia. The research objectives were to investigate the utility of a pain assessment tool (Pain Assessment in Advanced Dementia scale, PAINAD [3]) and a distress assessment tool (Disability Distress Assessment Tool, DisDAT [4]) in a UK population with severe dementia; to demonstrate the ability of the tools to measure change in pain following a change to the management regime; to assess the nature of distress that may produce a false positive result on a pain scale and to examine the use of analgesia within the nursing homes and in those identified as experiencing pain. The PAINAD was chosen for use as it is based on a well-validated scale and changes in scores have been demonstrated on

analgesic administration. The DisDAT was chosen for use as it identifies distress rather than just pain and allows unique behaviours to be documented. The two assessment scales were chosen, therefore, because they offered a related but contrasting approach. Whereas PAINAD stipulates the behaviours to be observed, DisDAT allows unique behaviours to be described for individuals.

**Methods:** A pilot study was undertaken involving nursing home residents with advanced dementia, defined as a Clinical Dementia Rating (CDR) score of three. Proxy assent was gained from relatives. Demographic data was collected and background neuropsychiatric scales were completed by nursing home staff. These were the Cornell Scale for Depression in Dementia (CSDD), Clifton Assessment Procedure for the Elderly-Behaviour Rating Scale (CAPE-BRS), Neuropsychiatric Inventory (NPI) and the Cohen-Mansfield Agitation Inventory (CMAI), completed to assess the levels of depression, dependency, psychopathology and agitation of the study participants. The participants were observed at rest, during a meal and at a time of intervention by the researcher and a nurse. The pain assessment tool and distress assessment tool [3] [4], were completed following the observation. The participants who were felt to be in pain were assessed regarding the cause of their pain. This was achieved by reviewing medical and nursing notes, by discussion with nursing staff and GPs, and by physical examination if necessary. Appropriate management was then suggested, utilising non-pharmacological and pharmacological strategies. Those who scored above two on the PAINAD scale (indicating possible pain) but were felt not to be in pain formed the false positive group. Both the participants with pain and the false positive group were reassessed at one month

and again at three months using PAINAD and DisDAT. The background neuropsychiatric scales were also repeated at the one month stage. A second researcher also carried out the observations using the same assessment tool as the researcher to provide evidence of inter-rater reliability. All statistical methods were undertaken using SPSS-14. Associations between categorical data were analysed using Fisher's exact test, associations between numerical and categorical data were analysed using the Kruskal-Wallis test. Paired observations were analysed using the Wilcoxon signed ranks test.

**Results:** 79 participants completed the study, 72% were female and the mean age of the sample was 82. 13 participants found to be in pain. A further 26 participants had a PAINAD score of above two, but were not felt to be in pain. These results gave PAINAD a sensitivity of 92% and a specificity of 61%. The pain identified had a variety of causes with both acute and chronic pain being identified. The majority of the pain identified was musculoskeletal in origin. Many of those found to be in pain were already taking analgesics, suggesting that pain in this group may be under-treated. The pain identified was managed both by non-pharmacological and pharmacological techniques. A significant difference was demonstrated in both PAINAD and DisDAT scores on intervention following treatment for pain (both significant to  $p = 0.008$ ). A significant difference in the background neuropsychiatric scores was not demonstrated. The majority of the behaviour observed in the false positive group seemed to be caused by the participant not understanding what was happening, leading either to fear and anxiety or to anger and frustration. The inter-rater reliability of the tools varied from fair to worse than by chance.



**Conclusions:** Pain was not as common as had been assumed from previous research. The behavioural pain assessment tool (PAINAD) identified behaviours that were not caused by pain, thereby questioning its use as a tool solely to identify pain. As a significant difference was demonstrated in both PAINAD and DisDAT scores once treatment for pain was implemented, these tools can be used to assess effectiveness of interventions to treat pain. As worsening of chronic pain conditions or new slow onset pain complaints had not been identified, regular use of behavioural assessment tools in all of those with severe dementia is recommended. This should form part of a thorough overall assessment, in order to help to raise a question concerning a person's behaviour, and in particular, whether that behaviour signifies pain. This work was a pilot study; further studies need to be carried out to assess the potential impact on pain by the regular use of behavioural assessment tools, to address issues regarding inter-rater reliability and to define an optimum time period for behavioural observation in this patient group.

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## **Abbreviations**

ACC	- Anterior Cingulate Cortex
AD	- Alzheimer's disease
ADD	- Assessment of Discomfort in Dementia protocol
ADL	- Activity of daily living
BNF	- British National Formulary
BPI	- Brief Pain Inventory
BPSD	- Behavioural and Psychological Symptoms of Dementia
CAPE-BRS	- Clifton Assessment Procedure for the Elderly-Behaviour Rating Scale
CDR	- Clinical Dementia Rating Scale
CSDD	- Cornell Scale for Depression in Dementia
CMAI	- Cohen-Mansfield Agitation Inventory
CNPI	- Checklist of Non-verbal Pain Indicators
CBT	- Cognitive Behavioural Therapy
CT	- Computerised Tomography
DisDAT	- Disability Distress Assessment Tool
DLB	- Dementia of Lewy Body type
DNR	- Do Not Resuscitate
DoH	- Department of Health
DS-DAT	- Discomfort Scale for patients with Dementia of the Alzheimer Type
DSM	- Diagnostic and Statistical Manual
DVT	- Deep Vein Thrombosis

EEG	- Electroencephalogram
EMI	- Elderly Mentally Infirm
ESMI	- Elderly Severely Mentally Impaired
FAST	- Functional Assessment Staging
FLACC	- Face, Legs, Activity, Cry, Consolability Scale
fMRI	- Functional Magnetic Resonance Imaging
GP	- General Practitioner
HIV	- Human Immunodeficiency Virus
LCP	- Liverpool Care Pathway
MDS	- Minimum Data Set
mg	- Milligrams
MMSE	- Mini-Mental State Examination
MOBID	- Mobilization-Observation-Behaviour-Intensity-Dementia pain scale
MSSE	- Mini Suffering State Examination
NHS	- National Health Service
NOPPAIN	-Non-Communicative Patients Pain Assessment Instrument
NPI	- Neuropsychiatric Inventory
NRPS	- Nurse reported pain score
NSAID	- Non Steroidal Anti Inflammatory Drug
PACA	- Palliative Care Assessment Tool
PACSLAC	- Pain Assessment Checklist for Seniors with Limited Ability to Communicate
PADE	- Pain Assessment for the Dementing Elderly

<b>PAINAD</b>	- Pain Assessment in Advanced Dementia
<b>PEG</b>	- Percutaneous Endoscopic Gastrostomy
<b>PLPH</b>	- Post Lumbar Puncture Headache
<b>PPC</b>	- Preferred Place of Care
<b>PRN</b>	- Pro Re Nata (as required)
<b>SRPS</b>	- Self-reported pain score
<b>TENS</b>	- Transcutaneous Electrical Nerve Stimulation
<b>VAS</b>	- Visual Analogue Scale
<b>VaD</b>	- Vascular dementia
<b>WHO</b>	- World Health Organisation

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## **Chapter 1 ~ INTRODUCTION**

This thesis records a pilot study; the main aim of which was to demonstrate the importance of managing pain as part of good quality palliative care in people with severe dementia. There were four objectives of the research namely: to investigate the utility of a pain assessment tool and a distress assessment tool in a UK population with severe dementia; to demonstrate the ability of the tools to measure change in pain following change to management regime; to assess the nature of distress that may produce a false positive result on a pain scale; and to examine the use of analgesia within the nursing homes and in those identified as experiencing pain.

In the remainder of the introduction, I shall initially provide brief background information on dementia; secondly, describe the issues that arise in connection with palliative care in dementia; thirdly, discuss pain as a symptom arising in dementia; before, fourthly, considering the assessment of pain in dementia; and finally, reviewing the possible management of pain in people with dementia. The background and introductory remarks will serve to underpin the aims and objectives of my study, which are reiterated in the conclusion of the chapter.

### **1.1 Background**

Life expectancy is increasing in European and other developed countries with greater numbers of people living beyond 65 years of age. The reduction in deaths from infectious diseases in infancy and childhood over the past century has led to many surviving into

old age and dying from a different spectrum of diseases. As more people die as a result of serious chronic diseases, a different range of physical, psychological and social problems is encountered [5]. Currently, 16.1% of the UK population is over 65, this is set to rise to 24.1% by 2050 [6].

Dementia currently affects approximately 37 million people worldwide, with an estimated 775 000 cases in the UK [7]. It affects 5% of those over 65 and 20% of those over 80 [8]. The prevalence of dementia rises exponentially with age, doubling in rate every five years. Hence the number of those with dementia is expected to rise with an ageing population, with cases in the UK predicted to rise to 1.7 million by 2051 [8]. Dementia is a chronic progressive condition where there is a disturbance of multiple higher cortical functions including memory, orientation, comprehension, language and judgement. The impairments of cognitive function are commonly accompanied by a deterioration in emotional control, social behaviour and motivation [9]. Although the median length of survival from dementia diagnosis has been suggested to be eight years [10], recently published data based on a cohort study described median survival from estimated onset of dementia to be 4.6 years for women and 4.1 years for men [11].

Over 60% of dementia patients have Alzheimer's disease [8]. The condition was first described by Alois Alzheimer in 1906. It is characterised pathologically by neurofibrillary tangles and amyloid plaques as well as cholinergic neurotransmission dysfunction. Length of survival in Alzheimer's disease is highly variable, ranging from



two years to more than sixteen years, with a median survival of between 4.2 and 5.7 years [12].

Vascular dementias are the second most common type of dementia accounting for a further 10 to 20% of dementias. Cerebrovascular disease and ischaemic brain injury are the primary cause of deficits in vascular dementia. Morbidity and mortality are usually worse for vascular dementia than Alzheimer's disease, with survival around five years [13]. It is felt that up to 40% of dementia patients have an overlap of vascular and neurodegenerative pathologies.

Dementia with Lewy bodies accounts for a further 10-20% of dementia. This is a primary degenerative dementia with pathological features of both Alzheimer's disease and Parkinson's disease (Lewy body formation). Other less common types of dementia in older people include frontal lobe dementias, dementia in Pick's disease, Creutzfeld-Jacob disease, Huntingdon's disease and HIV related dementia [13]. Alzheimer's disease is more common in women, while vascular and mixed dementias are more common in men [8].

## **1.2 Palliative Care in dementia**

Progressive dementia is an incurable illness and until recently, was viewed as a "living death" about which little could be done other than custodial care [14]. In common with other progressive life threatening conditions, it has been recognised that the principles of palliative care may apply to patients with dementia [1, 15, 16]. Palliative Care is defined

by the WHO as, “the active total care of patients whose disease is not responsive to curative treatment” [17]. Control of pain, of other symptoms, and of psychological, social and spiritual problems is paramount. The goal of palliative care is to achieve the best quality of life for patients and their families.

The hospice movement was initially developed in response to the perceived needs of terminally ill cancer patients [15]. During the 1990s it was increasingly recognised that cancer patients were not alone in needing palliative care; a report to the Department of Health in 1992 argued that “all patients needing them should have access to palliative care services” [18]. It is now a key principle in the guidance on the commissioning of palliative care services for adults that it is a right of *every* person with a life-threatening illness to receive appropriate palliative care wherever they are. This principle has been endorsed by several influential institutions including the National Institute for Health and Clinical Excellence, the Royal College of Physicians and the National Council for Palliative Care [7, 19, 20]. Despite this important shift in emphasis, the reality is that most patients who access hospice and specialist palliative care in the UK have cancer. Between 1-2 % of patients admitted to hospice have dementia as their primary diagnosis [10, 15] and dementia patients are infrequently referred to hospital or community palliative care teams [21, 22]. In addition, palliative care teams may not regard such patients as having specialist needs or be appropriate for their service [23].

One aspect of palliative care is the management of symptoms including pain. Pain can be defined as an unpleasant sensory and emotional experience [24]. It is a complex

phenomenon derived from sensory stimuli or neurological injury and modified by individual memory, expectations and emotions [25]. Although there are no reliable (or specific) biological markers of pain, an individual's description and self report usually provides accurate, reliable and sufficient evidence for the presence and intensity of pain [26]. In summary, pain is whatever the experiencing person says it is and it exists whenever they say it does [27]. If the person is in the terminal stages of dementia with corresponding communication difficulties, then the ability to self-report and describe pain is diminished. This could therefore lead to the under-recognition of pain in this group.

These concerns regarding pain management in those with dementia have been borne out in multiple studies. Research simply involving elderly nursing home residents with varying levels of cognitive impairment have demonstrated that between 45-80% will describe substantial pain [28-30] which is often under-treated [2]. It is therefore a major concern that there may be considerable numbers of patients with severe dementia with undetected and untreated pain. The development of effective means of recognising and evaluating pain in this vulnerable population is hence of great importance [31].

### **1.2.1 The palliative needs of patients with dementia**

As dementia is a chronic, progressive, often incurable condition it would therefore seem reasonable that palliative care principles should be applied when managing the condition. Although there is a wide variation in the course of the illness among individual patients, there are groups of signs and symptoms that herald the final stages of dementia. There is a progressive worsening of memory, with increasing confusion and disorientation.

Behavioural changes are seen in addition to a progressive deterioration of speech with the patient eventually becoming mute. There is also a loss of mobility, with the patient becoming bed-bound and totally dependant. Appetite and ability to swallow are lost and hence aspiration becomes a risk. As a consequence of these neurocognitive, functional and nutritional deficits, bladder and bowel incontinence develop, infections become increasingly common and decubitus ulcers may also occur [10, 16, 32, 33].

Some of these issues have been demonstrated by work carried out by interviewing those caring for someone with dementia in the last year of their life. This work also provided information about the needs of those dying from dementia and contrasted this with those dying from cancer. McCarthy *et al* carried out a retrospective survey of carers or family members who knew about the last year of life of those dying from cancer or dementia (as identified by death certification) [34]. They identified 170 dementia patients and 1513 cancer patients and gathered information from the carers or relatives. None of the dementia patients had died in a hospice; however, 13% of the cancer patients had died in a hospice. This was a statistically significant finding. The dementia patients suffered from multiple symptoms in the last year of life; most common were mental confusion, urinary incontinence, pain, low mood, constipation and loss of appetite. Similar frequencies were reported for cancer patients, but dementia patients experienced these symptoms for a longer period of time. Dementia patients saw their GPs less often than the cancer patients and the levels of assistance needed at home were greater for the dementia patients. Although the study was retrospective in nature, which may make the findings less valid,

it clearly highlights the symptom burden experienced by those with terminal dementia and contrasts this with the supportive care experienced by those with cancer.

Similar work was carried out by Mitchell *et al* in New York State [35]. They used the Minimum Data Set (MDS) to compare 883 nursing home residents with terminal cancer (less than 6 months life expectancy) with 1609 residents with advanced dementia (Cognitive Performance Scale 5 or 6) who died within a year of admission to the nursing home. They compared the data derived from the admission MDS with the last MDS that was completed for the resident before death for the two groups. Six months after admission, 92% of the cancer cohort had died and 71% of the dementia group had died, however only 1.1% of the dementia group were perceived as having a life expectancy of less than 6 months on admission. This may reflect the difficulty in identifying the terminal phase of dementia or, alternatively, that advanced dementia is not considered to be a terminal illness. These issues were probably also a factor leading to fewer “do not resuscitate” (DNR) orders being made for those with dementia as opposed to those with terminal cancer.

In addition, those with dementia were less likely to have had “do not hospitalise” and “not for tube feeding” orders made. Various “non palliative” interventions were more common for those with dementia compared with those with cancer, such as phlebotomy and intravenous therapy. The study also looked at symptom levels and although pain, shortness of breath and constipation were documented, the levels were significantly lower than experienced by those with cancer. This may be a consequence of the inability of

those with dementia to self-report their symptoms. Pressure ulcers and fever were much more common in those with dementia, possibly owing to the level of prolonged debility experienced by those residents. Although there may be inaccuracies in how MDS data is collected, this study highlights the range of symptoms that those with dementia may experience and the difficulty in recognising the terminal stage of dementia.

These studies demonstrate not only a role for palliative care surrounding symptom relief, but other aspects of end stage dementia care that may benefit from palliative input. As the disease progresses and more functions are lost, decisions have to be made regarding levels of medical intervention. This may involve placement of PEG tubes, whether to treat recurrent infections or whether to resuscitate in the event of cardio respiratory arrest. Providing psychological, social and spiritual care, an essential part of palliative care, is also important in dementia care, as is supporting the families of those with dementia. Finally providing good quality end of life care, wherever that may need to take place, is an important challenge for all those involved in dementia care.

#### **1.2.1.1 Feeding difficulties**

As dementia progresses, a large proportion of patients will develop feeding difficulties. Maintaining independent feeding requires a variety of skills, with a functional swallow being only one of the necessary components [36]. Research using video-fluoroscopic techniques has suggested that up to 93% of those with advanced dementia will have some degree of dysphagia [37]. These feeding difficulties can cause multiple problems including aspiration pneumonia, weight loss and malnutrition, with subsequent inability

to fight off infection. Conservative strategies for managing this common problem can be successful. Avoiding drugs that cause xerostomia, careful attention to dental care, use of finger food and nutritionally enhanced food as well as increasing personal assistance with meals, may all be beneficial [38].

As with many other conditions that can lead to dysphagia, PEG feeding can be considered to provide nutritional support [39]. The intention of feeding tube placement is to prevent aspiration pneumonia, forestall malnutrition and its sequelae and to provide comfort [38]. There is little evidence to suggest that tube feeding prevents aspiration pneumonia in those with severe dementia as aspiration of oral secretions or regurgitated gastric contents is not necessarily avoided [40]. In addition there is relatively sparse data to demonstrate that malnutrition is prevented. There is evidence that tube placement itself can cause death with peri-operative mortality rates for PEG placement of between 6 to 24% and a poorer prognosis for those with dementia who have PEG placement compared to other age matched groups [39]. Other work, examining survival rates in patients with dementia referred for PEG tube placement, demonstrated that those who did not undergo the procedure had a median survival similar to those who did [41]. Additional research has also demonstrated little impact on long-term survival by the use of feeding tubes in those with advanced dementia [42], although prolonging survival may not necessarily be the long-term goal in those with advanced dementia. It is possible that, by the time many of those with severe dementia are referred for tube placement, they are already malnourished [43]. This may therefore put them at a greater operative risk and make them less likely to gain survival benefit from tube placement.

### **1.2.1.2 Treatment of recurrent infections**

Recurrent infections occur in those with dementia for a variety of reasons. There is evidence to suggest immune responses are reduced in advanced dementia [44], decreasing the ability to resist development of infection. Incontinence and urinary retention may lead to an increased risk of urinary tract infections. There is an increased risk of developing pneumonia caused by swallowing difficulties and decreased mobility. Other infections may also develop such as infected pressure sores caused by impaired ambulation [16]. It may also be more difficult to diagnose infections due to a lack of reporting of symptoms, which is seen even in those with early Alzheimer's disease [45].

The issue of when to treat pneumonia in those with severe dementia is controversial. Bronchopneumonia is the commonest cause of death for those with Alzheimer's disease [46] so it could be argued that the development of pneumonia is a terminal event. Morrison and Siu [47] compared 80 patients with end stage dementia to 39 cognitively intact age matched patients who were admitted to a New York hospital with pneumonia. Both groups received similar management for their illness in terms of investigations and antibiotics. They found that 53% of the dementia group had died within 6 months of admission compared with 13% of the cognitively intact group.

Van der Steen *et al* [48] compared outcomes of 374 nursing home residents with dementia who developed pneumonia and were treated with antibiotics. They found that dementia severity was significantly related to death rate within the first week of



pneumonia being diagnosed. In addition, dementia severity was significantly related to death within three months of the pneumonia diagnosis. It would therefore seem that those with dementia, particularly those with severe dementia, have poorer outcomes from episodes of pneumonia despite antibiotic treatment. Others have attempted to examine whether treating infections provides survival benefit. Fabiszewski *et al* [49] demonstrated that the mortality rate from episodes of fever was significantly higher in those not treated with antibiotics (who had their symptoms palliated) than those given antibiotics. By controlling for the level of disease, they demonstrated that for the more severely affected patients, there was no difference in survival probability between the two groups. It is worth highlighting that in this study, a third of fevers documented had no obvious infective cause, making it difficult to equate the frequency of fever with infection rate. The study discusses the invasive nature of investigation for infections; however, such procedures as suctioning to gain a sputum sample are not common practice in the UK. The argument therefore that the investigation of infections itself causes suffering is less relevant. In addition, conclusions reached regarding the futility of antibiotic treatment for those with severe dementia is dependant on whether the methods used for controlling for the level of disease were appropriate.

Whether giving antibiotics provides some symptom relief, even if it does not cure the underlying infection, is a contentious issue. Volicier [50] argues that patient comfort can be ensured by the liberal use of antipyretics and analgesics even if the infection is not treated with antibiotics. Van der Steen *et al* [51] used the Discomfort scale for patients with Dementia of the Alzheimer type [52] to evaluate levels of discomfort in nursing

home residents with dementia who developed pneumonia. They demonstrated that the level of discomfort was higher in the patients that had had antibiotic treatment withheld; however their levels of discomfort were higher generally before the pneumonia was diagnosed. Although it is not clear from this study what palliative interventions the nursing home residents received, it demonstrates the difficulties in deciding whether prescribing antibiotics in pneumonia concurs some symptomatic benefit. This leads to wide variation in practice, for example, between Dutch and US nursing homes [53]. Similar issues arise with treating other infections: do antibiotics provide some symptomatic benefit or do they simply cause increased discomfort and prolong the terminal phase? Although there can be difficult decisions to make regarding the treatment of infections in those with end stage dementia, careful discussion to weigh up the benefits and burdens of any treatment is always important.

### **1.2.1.3 Resuscitation**

Difficulties may also be encountered in making resuscitation decisions for those with advanced dementia. The previous UK guidelines regarding resuscitation for patients were frequently a source of confusion amongst clinicians [54] as they contained many contradictory statements and lacked a framework for decisions to be made. A recent joint statement from the British Medical Association, Resuscitation Council and Royal College of Nursing has been published to clarify decisions relating to resuscitation [55]. Hence if the clinical team believe that resuscitation will not restart the heart and maintain breathing, it should not be offered or attempted. If, however, resuscitation in the event of

an arrest might be successful, then the benefits of prolonging life must be weighed against the potential burdens. In these circumstances, discussion with the patient is an essential part of the decision-making process, but is not feasible with a patient with advanced dementia lacking the capacity to consent to resuscitation. In England and Wales the decision should be based on a proper and careful estimation of what might be in the person's best interests in accordance with the provisions of the Mental Capacity Act 2005 [55, 56].

The outcomes for cardiac arrest in a nursing home are poor. Zweig [57] reported that survival to discharge from an acute care hospital after cardiac arrest in a nursing home ranged from 0 to 5% and was lower if the arrest was un-witnessed. This is based on work carried out in the US where resuscitation practices in nursing homes are better developed [58]. In hospitals, resuscitation is three times less likely to be successful in patients who are cognitively impaired and the success rate is almost as low as in metastatic cancer [59]. It has been demonstrated that most cognitively intact older adults (95%) would not want cardiopulmonary resuscitation if they had severe dementia [60]. Even if resuscitation is successful, two thirds of survivors from community arrests have new neurological or functional deficits [58].

There are, therefore, several very difficult treatment decisions that often have to be made during the course of a patient's illness. Distress can occur surrounding these decisions because of the long course of the illness, the patient's reduced capacity to have input into them, stress of the caregivers and underestimation of the terminal nature of advanced dementia [16]. As similar issues occur in those with other terminal illnesses such as

cancer and motor neurone disease, palliative care teams may be able to offer advice and support regarding difficult decision-making processes [5]. The treatment decisions that may need to be made all involve balancing benefits and burdens to the person and therefore all need to be made on an individualised basis. The person's wishes, if known, are central to the decision-making process. Advance care planning is increasingly promoted to allow such wishes to be documented [20]. Around 11% of those dying of dementia in a US study have made a living will [35]. Research evaluating advance care planning in nursing homes has demonstrated a decrease in hospital admissions and the mortality of nursing home residents [61], as well as increased satisfaction of patients' families [62]. Early discussion of diagnosis could enable those with dementia to express their wishes when mentally capable [63], thus allowing more person centred care to be delivered in the terminal stages.

#### **1.2.1.4 Family support**

Providing support to family members during a terminal illness forms an integral part of palliative care philosophy. Caring for someone with advanced dementia can be emotionally and physically exhausting. Often marked stress is caused by a diminishing capacity to participate in relationships as the carers lose the person they knew [10, 16]. This stress may be exacerbated if the dementia produces difficult behavioural symptoms. As a patient deteriorates, nursing home placement may become necessary. Despite this clearly being appropriate for the patient's needs, it can induce feelings of guilt and ambivalence. Once the person with dementia dies, their caregivers may need bereavement support particularly if the grief is complicated.

Albinsson and Strang asked dementia care and palliative care nursing staff what the most important measures for supporting families were [64]. Both groups highlighted giving information and listening to families. Owing to the longer disease trajectory in dementia, the rate that the information needed to be given was different. A lack of information about the natural course of the disease can make it difficult for families to anticipate future events, hence families may insist on hospital admission for acute illnesses in their relative with dementia [65]. Research carried out by Engel *et al* [62] demonstrated that few families of those with dementia recognised when their relative was in the final six months of the illness. Other issues highlighted by dementia care staff in the research by Albinsson and Strang included the provision of respite care, forming support groups for families and trying to relieve families' feelings of guilt. Although there were many similarities between the needs of the two groups, this research emphasises that supportive care for families needs to be specifically designed based on the trajectory and nature of dementia. Admiral Nurses may be well placed to give such support, however their services are not available country wide [63]. Support for families must, therefore, be provided from other sources, both professional and voluntary.

#### **1.2.1.5 Psychological, social and spiritual needs**

As those with dementia become increasingly dependant, aphasic and immobile, it is sometimes said that they only require physical care [33]. Palliative care involves not only attending to physical needs but also psychological, social and spiritual aspects to enhance quality of life as part of holistic care. In the study by McCarthy *et al* [34], two of the commonest symptoms described by carers caring for individuals with dementia were

mental confusion and low mood. Behavioural symptoms such as aggression, delusions, wandering, agitation and sleep disturbance are common in dementia, with over 90% of patients experiencing “behaviour disturbance” [66]. These non-cognitive symptoms seen in dementia are often described under the umbrella term of behavioural and psychological symptoms of dementia (BPSD).

Many of these symptoms form a syndrome that occurs after the onset of symptoms of dementia and vary over time [67, 68]. Evidence suggests that these symptoms are important determinants of patients’ distress, quality of life [69], carer burden and outcome in dementia. The symptoms are also important in leading to prescription of psychotropic drugs and nursing home placement [66, 68]. The recognition of particular symptoms can help to determine the underlying cause of the dementia. Multiple factors cause these symptoms, including the underlying brain disease, host factors and the environment. Thorough investigation of all the contributing dimensions is required in order to plan logical intervention [70], with treatment designed to address the underlying cause where possible [71]. Also important is the question as to why the behaviour is perceived as a problem, and therefore, treatment may need to encompass family and carers as well as the person with dementia [67].

Non-pharmacological interventions can be helpful, including behavioural therapies, exercise, music therapy and changes to the care environment. Providing quiet spaces and privacy within a home has been shown to reduce negative behaviours [72]. Antipsychotics, mood stabilisers, antidepressants and anxiolytics are commonly

prescribed for patients with dementia to address some of these symptoms; however there have been few clinical trials to support the use of these drugs in this patient group. Recent systematic reviews found that the evidence supporting the effectiveness of these drugs when managing BPSD is limited [70], although advising against them completely creates problems when managing those with severe behavioural disorders.

The recent document produced by the Alzheimer's Society, Kings College London and the London School of Economics [8] estimated that 63.5% of those with dementia lived in private households and 36.5% in care homes. The proportion of those residing in care homes increases as the condition progresses. In one study around 76% of those with dementia were institutionalised before death [73]. The Preferred Place of Care (PPC) document is a patient held record designed to record patient choices for all terminally ill patients [74]. To use such a document fully for those with dementia would require advanced planning, adequate resources and determination from all involved in caring for that person [33]. It is not clear to what extent the wishes of those with dementia are elicited when currently planning social support.

Spiritual care helps people in their search for hope and meaning, particularly as they face issues of grief, loss and uncertainty [75]. Although religion can form part of spirituality, it is possible for those without religious belief to explore the cause of illness and distress [76]. Essential elements of spirituality revolve around a relationship with self, others and God, a sense of meaning and purpose, hope, connectedness and beliefs. These issues become more urgent when people face crises of life [75, 77]; however, because of

cognitive changes, those with dementia may become dependant on others to maintain their spirituality [78]. In order to do this, those providing spiritual care need to see the whole person and join in that person's journey through the challenges they face [79]. Supporting the spiritual needs of families and carers is also important, as the suffering caused by dementia can last for many years with several losses experienced during that time. Despite the importance of spiritual care, the study by Sampson *et al* [21] demonstrated that very few patients with dementia admitted to hospital have their spiritual needs assessed or addressed. Although addressing such needs in those with severe dementia may be challenging, the spiritual needs do not stop with the onset of dementia [75].

The work of Kitwood has highlighted the importance of a person centred approach to caring for people with dementia. This approach emphasises the importance of those with dementia being viewed as a valued human and social being with moral worth and entitlement to human rights [80]. Those with dementia have the same needs as other people whether it is for physical comfort and care or for emotional, social and spiritual wellbeing [81]. Identifying and addressing the psychological, social and spiritual needs of those with advanced dementia will further the goal of improving care and hence quality of life.

#### **1.2.1.6 End of life care**

It has been suggested that people with dementia die in three different ways. They may die due to a medical condition unrelated to their dementia; others may die with a complex



mix of mental and physical problems consequent upon to the interaction between dementia and other conditions; or they may die from complications arising from end stage dementia [82]. Although the modes of dying may vary, ensuring excellent end of life care is of great importance.

Several studies have looked at issues surrounding end of life care for those with dementia. Professor Lloyd-Williams [83] carried out a retrospective case note audit of 17 patients with end-stage dementia on a psychogeriatric ward in 1996 to determine the most prevalent symptoms in terminal dementia (the last two weeks) and assess the palliation given. Pain and breathlessness were the most common symptoms that were documented in the notes and the palliation of these symptoms was variable. In particular, syringe drivers were not used even though patients were unable to take anything orally in the final 48-72 hours.

As many of those with dementia die in nursing homes, it is important to assess end of life care provided by such homes. This work has been carried out in Holland by Brandt *et al* in 2005 [84]. They used a Palliative care Outcome Scale, developed as an outcome measure for use with dying patients with advanced cancer and with their families, to assess end of life care. The nursing home staff completed the scale on a weekly basis for all those whose prognosis was felt to be six weeks or less. They demonstrated that the spiritual and psychosocial aspects of care were often not addressed when patients die in nursing homes. This seems likely to hold true for those dying in UK nursing homes.

Sampson *et al* compared the differences in care of those with and without dementia who died during an acute hospital admission in the UK [21]. They retrospectively reviewed 100 case notes and found that those with dementia were less likely to be referred to specialist palliative care teams and less likely to have had spiritual issues addressed. Similar work has also been carried out in the US by Ahronheim *et al* [85]. They reviewed 164 notes of patients with advanced dementia or metastatic solid tumour malignancy who died in a large teaching hospital. They found that those with dementia were more likely to have enteral tube feeding (51% had the tube in place when they died), the majority of both groups received empirical antibiotics in the last days or weeks of life and very few of those with dementia had made advance directives. Although there are clear differences in practise between the US and UK, particularly concerning tube feeding, these studies demonstrate the variety of issues surrounding end of life care for those with dementia which may be amenable to palliative input.

Attempts have been made to improve end of life care for those with dementia. Following the 1996 audit, Lloyd-Williams and Payne repeated the audit after the implementation of guidelines on management of common symptoms at the end of life [86]. The case notes of 27 patients who died on the unit were reviewed. There was an increase in the number of patients prescribed analgesics and fewer courses of antibiotics were prescribed in the last week of life following guideline implementation. The NHS End of Life Care Programme has been set up to improve the quality of care for people at the end of life ([www.endoflifecare.nhs.uk](http://www.endoflifecare.nhs.uk)). Three tools have been suggested by the programme. The Preferred Place of Care plan [74], as discussed earlier, is a patient held document

outlining the patients' thoughts about their care, choices they would like to make and where they would want to die. The Gold Standards Framework in Care Homes Programme [87] aims to identify, assess and plan care by promoting integrated collaborative working with primary care and specialist teams. The Liverpool Care Pathway [88] for the dying aims to take the best of hospice care for the last days of life into different care settings. It addresses issues surrounding communication, symptom control and psychological support at the end of life [7]. The use of the LCP for the dying is gradually increasing not only in hospitals and in the community but also in nursing homes where many with dementia die. Hockley *et al* looked at the benefits of implementing the tool in eight independent nursing homes in Scotland [89]. From interviews with nursing staff they found that the use of the LCP created a greater openness around death and dying, with dying being recognised more often. The staff also felt that teamwork and communication had improved and that they were using palliative care knowledge to influence practice. The study identified barriers to implement the LCP including high staff turnover and multiple GPs being involved in patients in the home.

In summary, as palliative care should be integral to all clinical practice involving chronic terminal disease, it is suited to the care of people with severe dementia [79]. Several studies have highlighted the needs of those with dementia [34, 35] including assessment and management of symptoms and issues regarding feeding, treatment of infections and resuscitation. Early discussion of such issues, when patients are mentally capable, could allow their wishes to be incorporated into the decision-making process [63]. Support for the family and friends of those with dementia is an integral part of a holistic approach to

care, as is addressing psychological, social and spiritual needs. All of these areas are fundamental to care at the very end of life, and recent care programmes have been designed to address these issues.

### **1.2.2 The timing of palliative care input**

As the palliative needs of those with dementia can be described, the question arises of when it is appropriate for palliative involvement for those with dementia to commence. It has been recognised that different conditions have differing theoretical trajectories of dying. Glaser and Strauss described three patterns of dying ~ abrupt and sudden death, expected death of varying duration (short term and lingering) and entry-reentry deaths (slow decline with frequent acute deteriorations) [90]. More recently these ideas have been expressed as a set of functional trajectories in which short term expected deaths (terminal illness such as cancer) are portrayed differently from lingering expected deaths (frailty) [91].

Work by Lunney *et al* [92] looking at activities of daily living (ADLs) of people in their last year of life demonstrated similar patterns to these theoretical trajectories, with those with cancer having a more predictable terminal period. Defining a terminal phase for cancer, however, can be problematic. One study looking at determining a terminal phase demonstrated that it can vary from between 1 to 1340 days [93]. Hence the period of active treatment and palliative care often overlaps [94]. The difficulty with a disease process such as dementia, which is often characterised by a gradual decline in functional ability, is to identify when a switch from active to palliative care is appropriate. Neither

approach is mutually exclusive but obtaining a timely balance between the two approaches may be difficult to judge [95]. A model where both curative and palliative treatments occur simultaneously could enhance quality of life and better manage end of life care [96].

Coventry *et al* carried out a systemic review in 2005 to try and identify tools and predictor variables that might aid clinicians to estimate survival and assess palliative status in non-cancer patients, including those with dementia [97]. Three studies were reviewed to determine prognosis in hospice based patients with dementia. One study used Functional Assessment Staging (FAST) using level 7C as a cut off point for hospice enrolment; equating to being virtually mute, dependant for all activities of daily living and unable to walk without assistance [98]. This was found to be a strong predictor of survival with a mean survival time of 6.9 months. However 41% of those studied could not be scored on this scale as their disease progression was not ordinal. Further work by this team [99] demonstrated that the non-ordinal patients survived significantly longer than those who deteriorated in a more predictable manner. Research published by Zvi Aminoff and Adunsky looked at identifying levels of suffering using a Mini-Suffering State Examination (MSSE) [100]. This research demonstrated that end stage dementia patients with higher MSSE scores had a shorter survival when compared to dementia patients with lower MSSE scores. The authors suggest that this group might benefit more from a palliative approach to their care. Defining what constitutes suffering is problematic and what is not clear is whether survival is improved if the causes of suffering as identified by the MSSE are alleviated. These studies demonstrate the

difficulties faced in trying to identify markers of a terminal phase for dementia that is applicable to all patients and when a more palliative approach is most appropriate.

Although it is important to recognise the terminal phase of dementia, it is clear that palliative care does not solely apply to those facing imminent death [101]. As those with dementia do not necessarily deteriorate in an ordinal manner, many of the palliative care issues discussed could potentially occur at any stage in the illness, not just in the last few weeks of life. Enabling those caring for people with dementia to recognise these issues as well as giving appropriate support from the relevant specialist teams will further the goal of providing adequate palliative care for all of those who suffer from dementia.

### **1.3 Pain in dementia**

To understand the issues surrounding pain in those suffering from dementia, it is beneficial to start by examining the issues surrounding pain management in an age-matched population with normal cognition or mild cognitive impairments. Several studies have attempted to quantify levels of pain amongst elderly populations and how well pain is managed.

#### **1.3.1 Pain in the elderly**

Ferrell *et al* [2] carried out a pilot epidemiology study of 92 nursing home residents with an average age of 88 and an average Mini Mental State Examination [102] of 20.7. They carried out semi-structured interviews, reviewed medical records and used two pain instruments, the Pain Experience Measure and the McGill Present Pain Intensity Scale. Interviews were carried out avoiding times within an hour of analgesia being given and focussing on the worst pain complaint and its character over the previous seven days. Sixty-five subjects (71%) indicated the presence of pain at least some of the time, 47% reporting intermittent pain and 24% constant pain. Twenty-two subjects (24% of sample) reported daily pain. The commonest source of pain was low back pain, followed by previous fractures, neuropathies, leg cramps and arthritic knees. Of those with pain, 54% reported that their pain impaired their ability to enjoy activities in the facility, as well as impairing ambulation and disturbing sleep. Only 15% of those with pain had received any analgesic medication in the previous 24 hours.

Won *et al* [103] carried out a cross sectional study of almost 50,000 nursing home residents who were over 65 with a MMSE of less than 19. Subjects were asked simple direct questions about pain. Daily pain was defined as any type of physical pain or discomfort in any part of the body occurring daily over the 7 days preceding the assessment. Over a quarter experienced daily pain and a quarter of those with daily pain received no analgesics. Residents who were over 85, male, black or mildly cognitively impaired were at the greatest risk of under-treatment.

An additional cross sectional study was carried out by Won *et al* [104] to understand analgesic prescribing patterns in nursing home residents by assessing 21,380 residents aged 65+ with persistent pain. They defined persistent pain as any pain recorded at least twice within 6 months by simple direct questioning of the residents. Almost 50% of the residents had persistent pain and the prevalence of persistent pain was very high in those with musculoskeletal pain and those with a history of falls, fractures or surgery in the past 6 months. Of those with persistent pain, 38.4% received opioids, 37.1% received non opioids and 24.5% received no analgesics. Additional studies [29, 32, 105-109] have identified similar levels of pain in both nursing home and community dwelling elderly patients.

### **1.3.1.1 The problems associated with managing pain in the elderly**

It would seem, therefore, that pain is a common problem in the elderly and is under-diagnosed and under-treated. There are multiple reasons why this might occur. Yates *et al* [110] used qualitative methods to investigate views of pain and pain management



practices held by elderly people living in long-term residential care settings in Australia. They found that many elderly people believed that it was common to experience pain and was a normal consequence of growing old. There was a perception that little could be done for their pain and they believed that pain is something that they should “put up” with. There were also concerns regarding worrying busy staff and being labelled as a “complainer”. Similar widespread stoicism in the presence of chronic pain was described in work carried out in UK nursing homes by Cairncross *et al* [108].

There may also be a perception amongst medical staff that pain is a normal consequence of aging and, hence, does not receive the attention that it should. There are misconceptions that older patients tolerate pain better or the perception of pain declines with age [111]. In addition, there may be concerns that medications suitable for younger patients cannot be used safely in the elderly. Until more recently, nursing homes have not prioritised pain assessment and management in the manner that occurs within acute care settings [112]. A study by Sengstaken and King [105] identified that often the non-detection of pain occurred owing to a failure of the treating physicians to inquire directly about the problem. There are also challenges regarding prescribing analgesics for the elderly. Older people are particularly susceptible to drug side effects with adverse drug reactions occurring twice as frequently in older than in younger patients. This effect increases with the number of drugs taken. On average older people take three times as many drugs as younger patients [113]. Alterations in pharmacokinetics in older patients can lead to varying oral bioavailability and differing drug distribution, owing to altered body composition and protein binding. Changes in metabolic clearance are also seen

owing to decreasing glomerular filtration rates and changes in the ability to induce liver enzymes [114]. In addition, changes to the number and affinity of receptors and impaired neurotransmitter production can lead to altered drug pharmacodynamics giving differing end organ responses to drugs [114]. The combination of lack of reporting by elderly patients, misconceptions by medical staff and difficulties regarding analgesic prescribing contribute to the under-recognition and under-treatment of pain in the elderly.

### **1.3.2 Pain in cognitively impaired elderly**

Although several studies have been carried out to ascertain levels of pain in elderly cognitively intact patients, there is a relative lack of evidence surrounding pain in those with cognitive impairment. This is more marked for those with severe dementia as this group is invariably excluded from studies into pain in those with cognitive impairment [115].

Ferrell's study of pain in nursing home residents excluded those with severe cognitive impairment [2]; hence this study is unable to provide information about their pain levels. A further study carried out by Ferrell *et al* [116] involved 217 nursing home residents with a mean MMSE of 12.1. The participants were interviewed about their pain, medical notes and charts were reviewed and the subjects were shown five scales to rate the intensity of their pain. In this study, 62% of the participants complained of pain, however 17% were unable to complete any of the scales presented. Although this study does involve those with a more marked cognitive impairment, 70 subjects were excluded from the initial sample as they were essentially mute and unresponsive and no meaningful

information could be obtained from the patient interview. Presumably many in this group were severely demented and again information regarding their pain experience is not provided.

A study carried out by Shega *et al* [117] of geriatric out patients involved a sample of patients with a mean MMSE of 16.6 who were interviewed regarding the levels of pain. From those interviewed, 32% reported experiencing pain at that point in time. Although this study provides information regarding levels of pain in those with moderate cognitive impairment, those unable to attend an outpatient clinic or who were unable to communicate were excluded. The study carried out by Won *et al* from 2004, of over 21000 nursing home residents with persistent pain, also excluded those with low MMSE scores and those unable to communicate [104]. Work carried out by Schuler *et al* [118] investigating the psychometric properties of the German PAINAD tool involved a sample of 99 nursing home residents with a mean MMSE of 12.9. They asked nursing staff to judge whether the participants were in pain during an observation period whilst the pain tool was also completed. The nursing staff concluded that 39.4% of the sample was in pain.

If those with severe dementia are being excluded from studies around pain caused by an inability to answer questions about their pain, then other methods of assessment need to be found. Horgas and Tsai [119] compared the analgesics prescribed for 155 nursing home residents with cognitive impairment with 184 residents without dementia diagnoses. They demonstrated that after controlling for the presence of painful

conditions, those with cognitive impairment were prescribed and administered significantly fewer analgesics than their cognitively intact peers. They also attempted to identify the factors linked to analgesic prescription and administration, highlighting that the more withdrawn and disorientated residents were prescribed significantly less analgesia. Unfortunately the two groups in this study were described in terms of having or not having a dementia diagnosis, rather than the level of their cognitive impairment. In addition simply having a potentially painful diagnosis does not always equate with having pain, hence it is difficult to draw firm conclusions from this work.

An alternative method might be to look at analgesics required by those with and without cognitive impairment following an event known to be painful and use this as a marker for levels of pain. Morrison and Siu carried out a prospective cohort study of elderly patients following a hip fracture [120]. Fifty-nine of the patients were cognitively intact and 38 had advanced dementia. They found that half the cognitively intact patients who experienced moderate to very severe pain were arguably prescribed inadequate analgesia for their level of pain. Less than 25% of this group had regular analgesia prescribed during their hospital stay. They also demonstrated that the cognitively intact group received on average three times as much opioid analgesia as those with advanced dementia (despite three patients of the advanced dementia group being managed without surgery.) A similar proportion of the advanced dementia group also did not have regular analgesia prescribed and had to rely on “as required” analgesia being administered for pain relief. The authors concluded that the inability of those with advanced dementia to self-report their experience of pain led to less analgesia being administered. They also

suggested that this group would have similar pain levels to the cognitively intact group, hence demonstrating under-treatment of pain in those with advanced dementia. One other possible explanation might be that pain is experienced differently in those with dementia, potentially accounting for some reduced levels of analgesic usage.

A similar study conducted by Feldt *et al* [121] used three measures to look at potential levels of pain in elderly patients following hip fracture surgery. They monitored opioid usage, a verbal descriptor scale to rate intensity of pain and the Checklist of Nonverbal Pain Indicators [122] to look at pain behaviours. A group of cognitively intact patients (35) and a group of cognitively impaired patients (53 with a mean MMSE of 12.1) were reviewed following surgery. Their levels of analgesic administration, pain intensity and pain behaviours at rest and during activity were recorded in both groups. A similar proportion of both groups were able to rate their pain intensity levels and this did not differ significantly between the groups. The cognitively impaired subjects again were administered significantly less opioid analgesia in the first four days post operatively than the cognitively intact group, despite prescribed amounts of opioid being similar for both groups. In addition, those with cognitive impairment scored significantly higher on the CNPI when being moved than did the cognitively intact patients. This suggests that the conclusions reached by Morrison and Siu [120] may well be correct, namely that pain is under-treated in cognitively impaired patients because of the inability of patients to report pain and the inability of those caring for them to recognise pain successfully. They suggest that this may be compounded by nursing staff being reluctant to administer

opioids owing to a fear of exacerbating or precipitating delirium in a patient with cognitive impairment.

There have been many studies published demonstrating the levels of pain in elderly patients and how this pain is often not recognised and not adequately treated. There are far fewer studies looking specifically at levels of pain in those with cognitive impairment and these studies do not include those with severe dementia. As those with severe dementia are often unable to communicate their level of pain, alternative methods of assessing levels of pain are required. The work looking at analgesic prescription in painful conditions has highlighted that prescribing differs depending on levels of cognitive ability. This may be caused by under-recognition of pain in this group of patients, but could also be caused by a change in pain perception.

#### **1.3.2.1 How pain is experienced in those with dementia**

As discussed previously there is evidence that pain is under-reported and under-treated in cognitively impaired elderly patients. There is little known about the effect of age alone on how pain is perceived. There may be age associated changes in transmission along A-delta and C nerve fibres; however it is not clear how this might affect an individual's experience of pain [123, 124]. The findings from experimentally controlled laboratory investigations are equivocal and variations seem to occur according to the type and intensity of noxious stimulation [125]. Work carried out by Gagliese and Melzack [126] by asking young and elderly chronic pain sufferers to complete the McGill Pain Questionnaire [127], demonstrated that there may be a difference in the quality but not

intensity of chronic pain. In general, age related changes in pain perception are probably not clinically significant [123].

Although it is clear that the ability to report pain is impaired for many patients with dementia, it may also be possible that there is an alteration in the perception of pain due to the effects of the dementing process on the brain. Pain is a construct incorporating sensory/discriminative components (identifying the injury in time and space), cognitive/evaluative components (how a response to a stimulus is influenced by culture, anxiety, attention and other factors) and affective/motivational components (protective processes to avoid injury) [128, 129]. The sensory/discriminative component of pain is chiefly mediated through the lateral pain system. The lateral pain system consists of spinothalamic tract neurons that project to the primary somatosensory area, parietal operculum and the insula via the lateral thalamus [130]. The cognitive/evaluative component of pain is mediated via the medial pain system, in particular the locus coeruleus and anterior cingulate cortex (ACC). The affective/motivational component is mediated through the medial pain system via the intralaminar and medial thalamic nuclei. Hence, relating neuropathological changes seen in dementia to the pathways of the constructs involved the pain experience may help in understanding how pain is experienced in dementia.

#### **1.3.2.1.1 Neuropathological changes in Alzheimer's disease**

In Alzheimer's disease the lateral thalamic nuclei are not significantly affected [131] and it is felt that the sensory/discriminative quality of pain perception may therefore be

preserved. Neuronal loss has been found in the locus coeruleus in Alzheimer's disease, as well as severe atrophy in the anterior cingulate cortex, potentially affecting the cognitive/evaluative component of pain. The affective/motivational component may also be affected as the intralaminar and medial thalamic nuclei, as well as the insula, have been found to be atrophied in the brains of those with Alzheimer's disease. The prefrontal cortex plays a role in the anticipation of affective painful stimuli and neuronal loss has been found in this area. In addition, the hippocampus and amygdala, both involved in memory for pain, have been found to severely atrophied in Alzheimer's disease. In summary most of the areas of the medial pain system seem to be affected in Alzheimer's disease [130]. This also includes memory as well as autonomic responses. Therefore, owing to the condition's effects on the medial pain system, a decrease in some of the components of pain might be expected.

#### **1.3.2.1.2 Neuropathological changes in Vascular Dementia**

In vascular dementia, infarcts can occur at many locations and hence could influence both the lateral and medial pain systems. These infarcts could alternatively provoke or ameliorate the suffering associated with pain [131]. Disruption of connections within the cortex and between cortex and sub-cortex by white matter lesions seen in vascular dementia can cause increased pain, termed central post-stroke pain. Hence it is possible that those suffering from vascular dementia suffer from an increase in pain.



### **1.3.2.1.3 Neuropathological changes in other dementias**

Less work has been done on other types of dementia. In dementia with Lewy bodies, atrophy and Lewy bodies particularly affect areas related to the medial pain system suggesting that many components of pain experience may be altered. In frontotemporal dementia more severe atrophy is seen in the frontal, lateral temporal and parietal regions. It is speculated, therefore, that the cognitive/evaluative and motivational/affective aspects are prone to deterioration in frontotemporal dementia [130].

### **1.3.2.1.4 Clinical evidence for neuropathological findings in Alzheimer's disease**

There is some research evidence in people with dementia that correlates with neuropathological findings. Fisher-Morris and Gellatly published two case reports of patients with Alzheimer's disease who had experienced physical trauma of various kinds [132]. Neither of the patients exhibited normal pain behaviour or gave verbal reports of pain commensurate with the tissue damage they had incurred. They then carried out a small scale national survey of abnormal pain experience in Alzheimer's sufferers by requesting reports via the Alzheimer Disease Society newsletter. They received 38 additional reports of patients failing to exhibit a normal pain experience in response to acute accidents, infections, acute surgical conditions and chronic conditions. A further nine reports were of the apparent disappearance of symptoms from diagnosed medical conditions. Although these reports were not verified, the authors felt that there was a subset of Alzheimer's patients who do not experience pain.

Porter *et al* examined the effects of venepuncture on several variables in 44 subjects with dementia (recruited from the Alzheimer's disease research centre) compared with 51 age-matched cognitively intact individuals [133]. They monitored heart rate at rest, whilst preparing for venepuncture, during venepuncture and in recovery. In addition they recorded levels of self-reported anxiety and pain by using a visual analogue scale before and after the procedure. They also video taped facial expressions and coded them using the facial coding system. The dementia group exhibited less of a heart rate increase during the preparation phase and a slight heart rate increase during venepuncture, whereas the cognitively intact group had a heart rate decrease during venepuncture. Facial expression was increased in demented individuals but could not be classified by specific emotions. The ability to respond to questions about anxiety and pain dropped markedly as the severity of the dementia increased. Only ten patients out of the total had Clinical Dementia Rating score [134, 135] of two or three and hence this may have altered the magnitude of the responses seen. The authors felt in conclusion that dementia influences both the experience and reporting of pain among elderly individuals.

Work carried out by a group in Italy demonstrated blunted autonomic responses to electrical stimuli in those with Alzheimer's disease [136]. In addition, Benedetti *et al* [137] demonstrated that pain anticipation and reactivity depended on both cognitive status and frequency bands of the EEG, whereas stimulus detection and pain threshold were not affected by the progression of Alzheimer's disease. They concluded that these findings demonstrated that the sensory-discriminative components of pain are preserved even in advanced Alzheimer's disease and that the cognitive and affective functions

(related to anticipation and autonomic reactivity) are severely affected. Further work by this group also suggested that owing to impairment in frontal lobe function seen in some with Alzheimer's disease, the expectation/placebo related mechanism of therapies for pain may be reduced [138].

Pickering *et al* [139] examined the differences in analgesic prescribing for acute and chronic pain in those with Alzheimer's disease compared with age match controls. They prospectively followed two groups of a 150 patients (with and without Alzheimer's disease) and documented analgesics administered for chronic pain conditions and acute pain episodes over a two year period. The frequency of acute pain episodes were similar for both groups, as was the amount of analgesia given to treat these episodes. The nature and number of chronic pain conditions in both groups were also similar, however the amount of analgesia administered was significantly less in the group with Alzheimer's disease. The authors postulate three possible causes for what was seen, that the group with Alzheimer's were unable to communicate their pain effectively, that the disease entities causing pain were less severe or that this demonstrates that the progressive effects of the dementia alters the pain experience of chronic pain. They point to the fact that the treatment of acute pain did not differ in the two groups, which suggests that perhaps there is a difference in how chronic pain is perceived in those with Alzheimer's. It is also possible, however, that the acute painful episodes that were described were much more easily identified as these may provoke an acute change in someone even if that person is unable to communicate. This would explain why the acute pain treatment levels were

similar. It is also possible that gradual worsening of chronic conditions may not provoke such noticeable differences and therefore explain why this was treated less.

Blennow *et al* [140] carried out a study of patients having a lumbar puncture as a diagnostic procedure for their dementia and looked at the incidence of post lumbar puncture headache (PLPH). All the patients were actively asked for symptoms of complications, including 86 with severe dementia. Only eight (2%) complained of PLPH compared with a published incidence in non-demented individuals of 24-38%. Unfortunately, information regarding the type of dementia these patients had is not described in the paper and there is a lack of information surrounding whether any of the patients were unable to respond appropriately to questions about their pain. It seems surprising that the 86 severely demented patients were all able to provide information about PLPH. The study would have benefited from having age-matched control patients as the incidence given in the paper for PLPH was derived from a variety of studies conducted by different groups several years previously, whose techniques may not have been comparable.

Despite these papers demonstrating some evidence that the experience of pain being less in those with dementia, recent work by Cole *et al* [141] using fMRI techniques to analyse responses to pain in patients with Alzheimer's disease showed that activity in both medial and lateral pathways was preserved. They also demonstrated increased activity in the dorsolateral prefrontal cortex compared with normal controls in response to pain. The authors felt that this may indicate an increased threat value of the pain for the patients on

account of their reduced ability to appraise the consequences of the experimental pain stimulus. The work was carried out with those in the early stages of their illness, but does call into question the evidence suggesting that the neuropathological changes affect the pain experience.

#### **1.3.2.1.5 Clinical evidence for neuropathological findings in vascular dementia**

Several studies have been published looking more specifically at pain levels in vascular dementia. A study carried out by Scherder *et al* [142] suggested that patients with possible vascular dementia suffered more pain than age-matched controls without cognitive impairment. The study involved 20 patients with “possible” vascular dementia and a control group matched for chronic pain conditions. They were asked to complete several different self-report scales based on current levels of pain and the CNPI [122] was also completed. There was a significant increase in scores on two of the self report scales in the group with vascular dementia, suggesting that those with vascular dementia suffer from more pain than those without cognitive impairment. It is worth noting however that as well as the numbers of participants being small, not all participants had had CT or MRI to confirm the diagnosis of vascular dementia.

Further work by Achterberg *et al* [143] examined the relationship between cardiovascular risk factors (hypertension and diabetes mellitus) and pain in those with cognitive impairment. They compared two groups of patients, all with cognitive impairment and at least one chronic condition likely to be painful and asked them to rate their pain over the last seven days. Those who had cardiovascular risk factors reported

more severe pain. It is very difficult to draw conclusions from this work as it is not clear what proportion of participants had vascular dementia, what the nature of the pain was (i.e. whether related to stroke disease, such as central post stroke pain, or caused by the painful condition originally identified) and which risk factor was more significant. It would therefore seem that despite theoretical reasons why those with vascular dementia may experience more pain, the current clinical evidence to confirm this is far from adequate.

Although it is useful to extrapolate information from cognitively intact elderly subjects regarding levels of pain, there is some evidence from neuropathological findings, case reports and experimental data that the pain experience for demented patients may be altered. More recent research has challenged some of these findings making it unwise to draw firm conclusions for all those suffering from dementia. Pain is a unique individual experience, as is the manner in which the disease progresses. It is, therefore, impossible to be certain whether a particular person with dementia will experience pain differently from someone without dementia. An important (and at times unappreciated) consequence of pain in those with dementia is fear. The memory of the social context and beliefs that would have modified the experience of pain may be lost causing those with cognitive impairment to be excessively frightened by pain episodes [131, 141, 144]. Therefore, even if some people with dementia may not appear to exhibit a normal pain response to a known painful stimulus, as described by Fisher and Gellatly [132], others may not only experience pain but also fear, greater than would be expected, in response to pain.

### **1.3.2.2 The link between pain and other variables in patients with dementia**

Quality of life for elderly people with dementia has been defined as involving cognitive functioning, activities of daily living, social interaction and psychological well being [145]. If one is aiming to improve quality of life by treating pain, then those factors that define quality of life should be improved by alleviating pain. A number of studies have been carried out looking at the links between pain and variables that relate to quality of life.

Cipher and Clifford carried out a study of 234 residents in nursing care who were referred to a geropsychologist because of a change in cognitive functioning, emotional distress or behavioural dysfunction associated with dementia [146]. By using scales to measure levels of pain, illness, depression, cognitive status, dysfunctional behaviours and resistance to activities of daily living (ADL), the authors found that cognitive, emotional and behavioural variables interact with one another to predict patients' activities of daily living. Pain levels were found to influence behavioural disturbances and depression which in turn influenced ADL, rather than being a direct influence. The authors concluded that decreasing pain is likely to yield the greatest overall improvements in ADL.

The study carried out by Won *et al* [103] in almost 50,000 nursing home residents used data from the MDS not only to assess pain levels but also the relationship between pain and mood, involvement in activities and ADL impairment. Pain was evaluated using observation and direct questioning and those with daily pain were included in the study.

Subjects suffering from daily pain were more likely to have mood disorders, ADL impairment and decreased involvement in activities. The authors do point out that this is purely an association and does not demonstrate direct causation.

Other studies look more at a specific variable and its relation to pain. Buffum *et al* [147] carried out a pilot study looking at the relationship between agitation and discomfort. They used scales to assess agitation, cognitive impairment, dementia severity and discomfort with a moderate positive correlation being found between discomfort and agitation scores. This might suggest that agitated behaviours indicate painful sensations. However, there is some overlap between the two scales (for example fidgeting on the discomfort scale is similar to restlessness on the Cohen-Mansfield Agitation Inventory [148]) which increases the chances of a positive correlation. There were also positive correlations between both discomfort scores and severity of dementia and agitation scores and severity of dementia. The authors felt that this implied that agitated behaviours should not be solely attributed to dementia as some of the behaviour might be due to discomfort. Further evidence of the relationship between discomfort and agitation was provided by a study carried out Pelletier and Landreville [149], which confirmed the findings of the pilot study by Buffum *et al*.

Parmalee *et al* [150] carried out a study of 598 nursing home residents to look at the relationship between pain and depression. They demonstrated a significant association between pain and depression, with those having criteria for major depression reporting more intense pain and a greater number of localised pain complaints than those with



minor depression or non depressives. The data also suggested that physical infirmity was not the sole factor underlying the correlation of pain and depression. The relation of depression to localised pain complaints was strongest where there was a physical disorder to which pain might be logically attributed.

Although there may be an association between pain and other variables, such as depression, agitation and levels of activity, relatively few of these studies look at this association with respect to those with severe dementia. Those which did were smaller in subject size or did not come to any definite conclusions. These studies all fail to demonstrate what happens when the pain is actively treated and whether this affects levels of depression and agitation. Ultimately if the goal of treating pain is to improve quality of life then observing a reduction in agitation and depression with an improvement in activity levels would be a valuable research outcome.

#### **1.4 The assessment of pain in dementia**

Several different approaches have been employed to assess pain in those with cognitive problems. One approach is simply to use self report pain assessment tools as might be used in the general population. Pain assessment tools such as Visual Analogue Scales, Verbal Rating Scales and Pain Faces Scales have been used in a variety of studies [116, 151-159] in elderly patients with varying levels of cognitive impairment. Some of these studies excluded those who were severely demented [155] or found that many scales could not be completed with worsening cognitive ability [116, 153, 156, 158, 159]. Other studies have demonstrated that at least one of the scales could be completed, but this differed from person to person, making it difficult to recommend one scale for all [151]. In addition it has been suggested that, owing to memory difficulties, those with cognitive impairment can only rate their pain at that moment rather than say how the pain has been over a period of time [157].

Similar conclusions were reached by Stolee *et al* in their systematic review of pain assessment tools for use in older persons with cognitive impairment [160]. They reviewed 30 self-report instruments and found completion in those with cognitive impairment varied between 20% and 100%. The higher completion of the self-report tools was found for those with mild to moderate cognitive impairments. There were no self-report instruments for which all major forms of reliability and validity testing were reported. These studies and reviews demonstrate that although some patients with severe dementia are able to complete certain self-report scales, this can vary tremendously. The validity and reliability of these scales for assessing pain in this population has not been

conclusively demonstrated. It would, therefore, seem logical to use a different method to assess pain than scales reliant on self-report. Behavioural assessment tools offer an alternative approach and have consequently been evaluated in this population.

#### **1.4.1 Behavioural pain assessment tools**

Pain has been characterised as “whatever the patient says it is and occurs whenever the patient says it does” [27]. This characterisation of pain is based on the premise that the sufferer can subjectively feel, cognitively interpret and clearly report the experience [161]. If this definition were to be followed to the letter, then it would follow that if patients could not express themselves, they would not be in pain. This definition is clearly unacceptable for use with confused or non-verbal elderly, but may explain why pain is frequently undetected in this group [162]. The loss of the ability to process, understand and describe internal experiences regularly leads to behavioural expressions of distress [163]. It would seem logical, therefore, to use behaviour to assess pain for those who are unable to express verbally what they are experiencing.

The use of such tools forms part of a framework of techniques to assess pain alongside self-report, a search for potential causes of pain, surrogate reporting and analgesic trial [164]. The American Geriatrics Society Panel on persistent pain in older persons recommended assessing pain in those with severe dementia by direct observation for pain behaviours [123]. This forms the first step of their algorithm for assessing pain, followed by meeting comfort needs, looking for underlying causes and considering an empirical trial of analgesia.

The idea of using observed behaviour for assessing pain is not new. Behavioural tools and observational procedures have been identified in the literature as methods of assessing pain in various populations from neonates to older adults [165, 166]. Such tools have a wide array of behaviours that can indicate pain including behaviours related to posture, facial expressions and change in functional ability. Although such tools could be used in patients with dementia, this assumes that the signs that are normally indicative of pain in a general population are also representative of pain in elderly patients with dementia. This assumption is doubtful given the identification of less obvious or atypical behavioural presentations in some people with dementia [167]. As a result, numerous tools to be used specifically in those with dementia have been developed over the past 15 years. Two assumptions underlie the development of such tools: firstly, that discomfort can be observed although it may not be verbally expressed; secondly, that those with dementia cannot voluntarily control their expressions or demeanour. Thus, observed behaviours can be considered external markers of internal states [52].

#### **1.4.2 Using behaviour to assess pain**

The work on developing behaviour-related pain tools for use with cognitively intact patients was greatly aided by the fact that these patients can report when they are in pain. Keefe and Block demonstrated that certain behaviours were correlated with reports of pain in cognitively intact adults with chronic low back pain [166]. With cognitively impaired patients who are unable to report their pain, there is no reliable method of knowing if what is being observed represents pain. If a certain procedure is known

usually to cause pain, it is therefore assumed that the behaviours observed during the procedure denote pain.

This principle was used in work carried out by Manfredi *et al*, who recorded the facial expressions and vocalisations that occurred during a dressing change of decubitus ulcers for nine severely demented patients [168]. This was then shown to medical students and nurses who had to infer the presence or absence of pain based on the vocalisations and facial expressions. Eight of the nine patients demonstrated facial expressions that were identified by observers as indicative of pain. The patient who was felt not to be in pain during the dressing change was the only patient receiving regular opioids. This study proposes that the facial expressions and vocalisations of demented patients suggestive of pain correlate with a procedure presumed to be painful. However, it is not possible to be absolutely certain that what was experienced by the patients' was pain as oppose to fear or anxiety. There is no evidence that behaviours resulting from pain are exclusive to that experience or are different to the behaviours that result from psychological causes such as anxiety [4]. Hence many tools designed to identify pain in patients with dementia may simply identify a negative emotion, one cause of which might be pain.

There is tremendous variability in the behavioural manifestations of dementia and the expected pain expressions that occur as a function of each person's unique damage to the brain [131, 169, 170]. This was demonstrated by Borod *et al* [171] who videotaped the facial expressions of patients with unilateral brain damage in response to emotionally laden slides. They showed that those with right sided brain damage used facial expression

in response to the slides less frequently than those with left sided damage and normal controls. Hence the variety of anatomical distribution of deficits in those with Alzheimer's and vascular dementia may lead to variation in many behavioural traits, as well as facial expression.

This variability in behaviour has been described by several authors, such as a patient becoming quiet and not eating when in pain [162]; and a patient laughing intermittently when in pain [172]. Pain assessment, therefore, needs to be uniquely tailored and individualised [169]. During the development of DisDAT by Regnard *et al* [4] it was identified that although some distress cues were common between patients, each patient had a distinct pattern of distress cues. This was also seen in the work by Parke [165] who interviewed gerontological nurses about how they recognised pain in cognitively impaired older adults. They described pain cues which were specific to the individual and were recognisable to nursing staff who knew them well. Using predetermined lists of potential pain behaviours runs the risk of missing important individualised cues and, as a consequence, the risk of not recognising when that person is in pain.

The use of behaviour related pain tools requires those working with demented patients to be able to identify behaviours that might indicate pain. Weiner *et al* [173] looked at the ability of nursing home staff and patients' families to identify pain behaviours reported by the patients themselves. The patients in the study all had chronic pain and were able to respond to pain questionnaires. They showed that the nurses' and the families' assessments of the residents' pain behaviours differed from the residents' assessments of

themselves. Agreement on pain behaviours between family and nurses was also poor. The authors felt that this might have a variety of causes. The staff might not be observing the patients at the moment the behaviour was occurring or they might have become desensitised to the behaviours if they occur chronically. In addition some of the pain behaviours might be displayed in patients who are pain free and hence might not be recognised appropriately in those who have pain. Other papers looking at pain behaviours in demented patients have discussed how nurses can accurately describe most of the residents' pain behaviours [162]. It has also been demonstrated, in a population of people with learning disabilities, that different carers will recognise different behaviours, with most able to recognise a core of behaviours for each patient [4].

#### **1.4.3 Challenges associated with using behavioural pain assessment tools**

A recent paper by Pautex *et al* [174] has questioned the routine use of behavioural scales in those with severe dementia. They asked 129 patients, with a Clinical Dementia Rating Scale of 3, randomly to complete a verbal rating scale, visual analogue scale and faces pain scale, whilst the nursing team completed the Doloplus-2 [175] behavioural rating scale. They demonstrated that 61% of the participants could complete at least one of the self report scales and the Doloplus-2 correlated moderately with the self-assessment scale. The Doloplus-2 underestimated severity when compared with self-assessment. This study can only really provide evidence around the utility of the Doloplus-2 scale, not all behavioural scales. It is, however, worth noting that studies comparing self report and behaviour assessment in those without cognitive impairment have found a low to moderate correlation between the techniques [176-178]. It has been suggested that self-

reporting pain intensity and pain behaviour comprise different aspects of the complex pain experience [177]. Others have discussed how behavioural expressions of pain, expected by clinicians, are often absent [179]. Both these factors may explain why behavioural scales do not always correlate well with self-report.

Although it is clear that behavioural tools are a sensible approach in identify pain in those with severe dementia, there are multiple pitfalls to this approach. There is no evidence for any behaviour that solely indicates pain [4], which could lead to an over-diagnosis of pain when the behaviour is due to a different cause. Pain behaviours are not unique from those that might indicate other problems such as boredom or depression [180]. The uniqueness of individuals and their disease means that a behaviour indicating pain in one patient may indicate contentment in another. Hence, there is a danger that important cues are overlooked or misinterpreted. The behaviours seen can be complex and difficult to capture adequately by behavioural tools not tailored to that individual [181]. Having behaviours on a scale that the person would not ever display runs the risk of their pain behaviours not scoring highly on a scale and therefore not being taken as seriously. Therefore, any scoring system attached to a behavioural scale is merely a representation of the number of behaviours seen, not an intensity rating [182]. Behavioural scales may measure a different aspect of the pain experience to self report [177] and may not be an accurate representation of the pain experienced, particularly if the person tries not to “show their pain”[179]. As some responses to chronic pain can be decreased activity, rather than an increase in certain types of behaviour, this may not be adequately identified on a uni-directional pain behaviour measure [170]. Finally, the tools rely on the abilities



of nursing staff to identify and interpret the behaviour correctly, which may be difficult owing to constraints on time or desensitisation [181].

Despite these potential problems, the concerns raised regarding the under-recognition and under-treatment of pain in this population have increased the drive to develop suitable assessment tools to identify pain [183]. Without the promotion of pain assessment tools, it is possible that many behaviours, caused by pain, may simply be ascribed to that persons dementia. Several reviews, although critical of aspects of current assessment tools, have emphasised that the use of behavioural tools in this population form an important part of assessing pain [31, 183]. Around 25% of nursing homes in a recent study were using a pain assessment tool to assess the pain of their residents [109]. Understanding how best to use such tools, as well as appreciating their limitations, is vital in developing strategies for assessing and managing pain in severe dementia.

Behavioural tools differ greatly in terms of evidence of validity, reliability and clinical utility. One review of 10 assessment tools concluded that currently there is no standardised tool that may be recommended for broad adoption in clinical practice [31]. Another review of 12 papers concluded that none of the scales was convincingly the most appropriate scale for assessing pain in elderly people with dementia [184]. A further review published recently [170] was again unable to recommend one tool for use across population and settings. From these reviews it is clear that more research is required to evaluate current tools. The difficulty lies in which tools to choose for further evaluation. Important factors influencing this choice are the strength of current psychometric

evaluation data, clinical feasibility of instruments and the support for use with the population of interest in specific settings [31]. Eleven published pain and distress assessment tools are summarised in the table overleaf.

*Table 1.1 Comparison of behavioural pain and distress assessment tools*

<b>Behavioural Assessment tool</b>	<b>Authors</b>	<b>Development</b>	<b>Subjects, setting</b>	<b>Administration, scoring, Feasibility</b>	<b>Reliability</b>	<b>Validity</b>	<b>Other issues</b>
Abbey pain scale	Abbey <i>et al</i> Australia 2004 [185]	Used work by on pain behaviours by other authors Modified by Delphi study and focus groups	Evaluated in 61 participants in long term care with late stage dementia	Nurses asked to use tool when pain suspected Tool claimed to take 1 minute to score	Internal consistency (Cronbach's $\alpha = 0.74$ ) was satisfactory Modest inter-rater reliability	Measured using scale score and nurse's holistic assessment, found to be "satisfactory"	Uses physiological indicators (no evidence for use in chronic pain) Equates behaviours with pain intensity
Assessment of Discomfort in Dementia (ADD)	Kovach <i>et al</i> USA 1999 [186]	Protocol using work on pain behaviours by other authors	Evaluated in 2 studies (104 & 143 participants) with severe dementia	Concerns that may be too complex for routine use [31]	Internal consistency not established. Varying levels of inter-rater reliability	Use of protocol lead to significant decrease in discomfort and increase in treatment	Unclear how long taken to complete protocol
Checklist of Nonverbal Pain Indicators (CNPI)	Feldt <i>et al</i> USA 2000 [122]	Developed from existing pain behaviour scale	Evaluated 53 in patients with hip fracture (mean MMSE = 12.2)	Score whether behaviour is or is not present	Moderate internal consistency, good inter-rater reliability	Tool possibly only valid for assessment of pain on movement	Not evaluated in long-term care facilities
Doloplus-2	Wray, Lefebvre-Chapiro <i>et al</i> France 1992 [175]	Adapted from pain scale for young children	Evaluated in a variety of settings but little info on subjects	Need to know patients well to complete	Good internal consistency, satisfactory retest reliability	Significant convergent validity	Unclear if English version psychometrically tested
Disability Distress Assessment Tool (DisDAT)	Regnard <i>et al</i> UK 2007 [4]	Developed from distress and contentment cues identified in subjects	Evaluated in subjects with severe intellectual disability, some with dementia	Carers recognised different cues Behaviour monitored using score sheets	Research currently being undertaken to establish psychometric properties	Research currently being undertaken to establish psychometric properties	Found to be simple to use and useful

<b>Behavioural Assessment tool</b>	<b>Authors</b>	<b>Development</b>	<b>Subjects, setting</b>	<b>Administration, scoring, Feasibility</b>	<b>Reliability</b>	<b>Validity</b>	<b>Other issues</b>
Discomfort Scale for patients with Dementia of the Alzheimer Type (DS-DAT)	Hurley <i>et al</i> USA 1992 [52]	Behaviours identified by nursing staff working in dementia centre	Evaluated in 2 studies (97+104 subjects) with advanced AD	Each item scored in terms of frequency, duration and intensity	Moderate retest reliability, satisfactory internal consistency (Cronbachs $\alpha$ = 0.79)	Significant correlations between DS-DAT and CMAI, VDS & discomfort thermometer	Well established in research setting but complex to use
Mobilization-Observation-Behaviour-Intensity-Dementia pain scale (MOBID)	Husebo <i>et el</i> Norway 2007 [187]	Developed from existing pain assessment tools and literature review	Evaluated in 26 subjects with MMSE $\leq$ 11 and with chronic pain	Subject observed and then gentle standardised movements performed. Also videoed	High internal consistency once items deleted. Variable inter-rater reliability	More pain identified using MOBID Higher pain intensity scores from watching video	Small sample size Difficulty in scoring certain domains for pain Concern that tool provokes pain
Non-Communicative Patients Pain Assessment Instrument (NOPPAIN)	Snow <i>et al</i> USA 2004 [188]	Developed by expert panel of clinical and research experts in pain and psychometrics	Evaluated in nursing assistants & in 83 subjects in nursing homes with severe dementia	Used at rest and movement Unclear how to interpret scores	Strong inter-rater reliability Low to moderate retest reliability	Low specificity scores Excellent agreement between videoed and recorded scores	Criticised for having limited comprehensiveness of non verbal pain behaviours [31]
Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)	Fuchs-Lacelle and Hadjistavropoulos Canada 2004 [189]	Behaviours identified by nursing staff to be indicative if pain	Evaluated by 40 nurses recalling a specific patient with limited ability to communicate	Checklist of 60 behaviours but no indication of how to interpret score	High levels of internal consistency but used nursing staff recall	Moderate correlation between scores and nurses global rating Rated as useful by staff in later study [183]	Reliability testing subject to recall bias Low internal consistency for some items in later study [183], item no. reduced [190]
Pain Assessment for the Dementing Elderly (PADE)	Villanueva <i>et al</i> USA 2003 [191]	Items developed after literature review, interviews and observations	Evaluated in 2 studies (25+40 subjects) with advanced dementia	Three areas assessed, physical behaviour, global assessment and ADLs	Variable retest reliability and internal consistency	Correlated significantly with CMAI Differentiated between pain and no pain	Complex using different scoring methods and time needed to complete
Pain Assessment in Advanced Dementia (PAINAD)	Warden <i>et al</i> USA 2003 [3]	Developed from existing pain tools including DS-DAT	Evaluated in 2 studies (19+25 subjects) with severe dementia	Five items scored from 0 to 2, giving a score out of 10	Moderate to good internal consistency High inter-rater reliability	Evidence of construct validity Pain scores lower during pleasant activity	Simple and easy to use Change in scores seen on treating pain

#### **1.4.4 Behavioural assessment tools used in this study**

The published behavioural assessment tools were reviewed before deciding which tools to use in the current research. The Abbey pain scale [185] was not chosen as it includes physiological change as a pain indicator. The autonomic nervous system responses have been shown to be altered in those with Alzheimer's disease [136, 137]; hence the inclusion of physiological change in the Abbey scale has to be questioned. In addition, physiological change is more commonly associated with acute pain rather than chronic pain [31]. The tool also equates the number of behaviours seen with pain intensity, despite the lack of published research demonstrating a correlation between pain intensity and number of behaviours [182]. The ADD [186] was not chosen as it is a protocol rather than a pain assessment tool, creating difficulties in comparing it to other tools. An important part of the research was exploring the use of tools at different times of the day, hence the CNPI [122], which may only be valid for movement related pain, was not chosen.

Other tools were excluded for different reasons. The Doloplus-2 tool [175] requires knowledge of the patients to be completed, thereby creating difficulties for the researcher to complete the tool. Research carried out in Norway [192] questioned the validity of Doloplus-2 in its present version. The PADE [191] was felt to be too complex and time consuming to use during every day care. The NOPPAIN [188] has been criticised for having limited comprehensiveness of behaviours [31], addressing only obvious pain cues. The PACSLAC tool [189] had not been used directly to observe patients at the time when the research was commenced and the MOBID tool [187] had not been published. This study uses two assessment tools, the Pain Assessment in Advanced Dementia scale

(PAINAD) [3] and the Disability Distress Assessment Tool (DisDAT) [4], the reasons for using these tools is discussed below.

#### **1.4.4.1 PAINAD**

PAINAD was developed by Warden *et al* in 2003 and is based on categories and behaviours from the Discomfort Scale for patients with Dementia of the Alzheimer Type (DS-DAT) [52] and the Face, Legs, Activity, Cry, Consolability scale (FLACC) [193] as well as on a literature review and consultation by experts in the field. DS-DAT was developed by Hurley *et al* and was first published in 1992. Several studies have demonstrated that it has good internal consistency, construct validity and test-retest reliability [194]. It is a well established tool [31], is often used in dementia research [48] and is the standard by which nearly all additional observational assessment tools in dementia have been evaluated [163].

However, it has some shortcomings. It has been found to be complex and difficult to use [194]. The tool requires extensive training to achieve acceptable inter-rater reliability, thus limiting its use as a clinical assessment tool in routine care. It only includes the most common behaviours thus potentially excluding more subtle indicators [31]. Despite these drawbacks it attained the highest score on a review of 10 behavioural assessment tools because of its reliability, validity, conceptual clarity and the subjects in which it has been evaluated [31]. It would, therefore, seem sensible to use assessment tools that are based on DS-DAT but are more easily administered, hence PAINAD was chosen.

PAINAD consists of five items including breathing, negative vocalisation and facial expression (see Appendix p322). Each item is rated on a three point scale with specific descriptions provided for each level of pain. There was a pilot testing phase where the terms were modified. The tool was then compared with DS-DAT and a Visual Analogue Scale for pain and discomfort by observing each subject for a five minute interval at rest, during intervention and during an activity which was pleasurable. In addition the PAINAD was used by clinical staff along with clinical judgement to assess participants who routinely received pain medication on an “as required” basis. The PAINAD was repeated 30 minutes after the pain medication had been given. Pain scores on the PAINAD were found to be lower during pleasant compared to adverse activities and the scores differed before and after pain modification [3]. The PAINAD has been found to be user friendly and requires minimal training time [195]. In the same study the tool correlated well with DS-DAT and the visual analogue scales. The internal consistency of the scale was found to be only moderate, however high levels of inter-rater reliability were attained. Furthermore, the sample size used to develop PAINAD was small and the pain scores tended to be clustered around zero [183], possibly because it only measured negative behaviours [3].

#### **1.4.4.1.1 Published studies utilising PAINAD**

Several studies have been published regarding the psychometric properties and utility of the PAINAD tool. In a report by Gibson *et al* [196], 80 nursing home residents (42 in high level care with a mean MMSE of 13.9) were assessed using the Brief Pain Inventory [197], PAINAD and Abbey [185] pain scales. They demonstrated only fair inter-rater

reliability, however internal consistency was found to be very good. Concurrent validity was assessed by comparing the Abbey and PAINAD scales with each other, however many of behaviours on each scale are the same; hence it was not particularly surprising that there was a strong concordance. There was a low agreement between BPI scores (completed by the participant) and the PAINAD scores, suggesting either that not all pain produces recognisable behaviour, or that the behaviours seen could not be found on the PAINAD scale.

Leong *et al* evaluated PAINAD in 88 nursing home residents with moderate and severe dementia [198]. Those who were included in the study needed to be able to answer queries about the presence and severity of pain as PAINAD was compared to a self reported pain score (SRPS), as well as a nurse reported pain score (NRPS). The PAINAD was completed by nurses recalling behaviours that the patient had exhibited in the last week. The NRPS was completed if the nurses felt that the patient had experienced pain in the previous week and the SPRS was completed if the patient, on asking, had described experiencing pain in the past week. The pain was graded using a four point verbal descriptor scale. A major correlation was demonstrated between the PAINAD and NRPS but this may be compounded by the fact that the same nurses completed both scales. Both the PAINAD and NRPS correlated poorly with the SRPS. The authors felt that this could be caused by SRPS measuring another aspect of pain, by it being an inaccurate measure or by it being confounded by another factor such as depression. It is not clear what other aspect of pain the authors felt self reporting measured. In addition, the work by Parmalee [199] has suggested that even those with marked dementia were able accurately to report



pain. This study also used the tool in a different way from how it was designed by only recording a score based on the nursing staff's ability to recall behaviour at weekly intervals, rather than by five minute direct observation. Furthermore, those who were recruited for the study were able to describe both presence and severity of pain, whereas PAINAD was designed for use with non-communicative patients. Although this study evaluates PAINAD in a larger population and demonstrates that PAINAD has an ordinal structure, there are concerns raised about the methods used and conclusions reached regarding PAINAD.

Hutchison *et al* [200] used PAINAD to identify pain in post operative patients. The study consisted of a control group of 53 participants and a PAINAD group of 27 participants, only 76% of the PAINAD group had a diagnosis of dementia. In addition, despite the entire control group having dementia; the control group all had an MMSE above 25. In the PAINAD group only a quarter had a MMSE score of less than 25. They demonstrated a higher opioid use in the group who had their pain monitored using PAINAD compared with the control group. The two groups were not matched in terms of dementia diagnosis or cognitive ability and hence any conclusions produced by the research are questionable. In addition, the practice of using a behavioural assessment tool in a group of patients most of whom, in view of their MMSE scores, were likely to be able to accurately self report their pain is dubious from the perspective of interest in people with severe dementia.

In a larger study carried out by Zwakhalen *et al* [183], the PAINAD scale was completed for elderly people with dementia, during a potentially painful situation (having an influenza vaccination) and at rest. They concluded that PAINAD had good psychometric qualities in terms of homogeneity, reliability and validity. This was measured either by nursing staff completing a Visual Analogue Scale or by a Verbal Rating Scale being completed by participants who were able to complete one. The authors acknowledge that alternative causes for the indicators that are included in PAINAD scale, such as anxiety or resistiveness to care, have to be excluded. This problem was highlighted by the work carried out by van Iersel *et al* [201] who introduced the PAINAD scale (as well as the Abbey scale) to nursing homes in Belgium. Many care providers felt that they were measuring pain with PAINAD. However, they were unsure if it was always physical pain rather than fear, anger or another cause. The authors questioned the use of consolability as an item on the scale as they felt that being able to console was the result of a treatment rather than an indication for it.

The scale has also been recently translated for use in Italian and German [118, 202]. The German version of the scale was used in 99 individuals with a mean MMSE of 12.1 at times of intervention by two different nurses [118]. Prior to the intervention a different rater had made a note of whether the individual was felt to have pain and rated the pain on a verbal rating scale. Following data collection, psychometric analysis demonstrated good internal consistency (Cronbach's  $\alpha = 0.85$ ) and inter-rater reliability of 0.8. The PAINAD scores were higher in residents who were felt to suffer from pain compared with those felt not to have pain, however the scores in those without pain were not zero.

In addition, the level of pain as rated prior to the observation did not correlate with the PAINAD scores.

A further concern raised by some authors is that the PAINAD tool has a limited range of indicators for pain. It is therefore possible that the PAINAD is unable to pick up subtle changes in behaviour which may indicate pain [170]. However, some reviewers of the scale felt it showed promise [163] and suggested that it needed further evaluation in a larger sample [31, 184].

In conclusion, PAINAD is itself based on a well-validated scale and is quick and easy to use. There is some research evidence for its psychometric properties with high levels of inter-rater reliability and moderate internal consistency. It has also been demonstrated that PAINAD scores change following analgesic administration. It was therefore chosen for further investigation in this study.

#### **1.4.4.2 DisDAT**

Some of the problems surrounding the use of behavioural tools (such as a lack of behaviours that only indicate pain and the possibility of missing unique behavioural responses) are addressed by the Disability Distress Assessment Tool (DisDAT) [4]. DisDAT was developed for use in people with intellectual disabilities and identifies distress. Once distress is identified then the cause is sought which can include pain as well as fear, anxiety and so on. The tool was not specifically developed for use in older people with severe dementia; however it has been used successfully with people with

Downs-related dementia. The tool is designed to be individualised to the patient, as the carers and family create a list of behaviours of distress and contentment specific to the patient from a checklist covering facial signs, skin appearance, speech, habits, and posture as well as body observations. It is also possible to record behaviours that are not listed that the person might display. The list of distress behaviours is then used as the assessment tool. In this way the subtle cues unique to the person can be identified by the assessment tool.

The tool has been investigated in practice with 56 carers completing the tool in 25 patients with profound communication difficulties. It was found that each carer recognised different numbers and types of distress cues, with a core of cues recognised by all raters. The carers expressed the view that each person had unique ways of showing that they were distressed but many cues were shared. Some cues were specific to a certain situation but many were non-specific and carers described a process of looking through various causes to interpret the cause of the distress. The majority of carers found the tool simple to use and useful in practice. Further work was carried out with the carers for ten patients exploring the meaning of distress for each of the carers. Some carers described it as solely a physical construct however the majority described a spectrum of distress including physical and emotional causes. The study by Weiner *et al* [173] demonstrated that “pain” means different things to different people when describing pain related behaviours. The behaviours of distress and pain as described in the literature were then compared in the paper by Regnard *et al* [4]. There is little difference between the two

groups of behaviours, demonstrating the difficulty in differentiating between pain and distress by solely observing behaviour.

The patients in the study demonstrated high numbers of identifiable distress cues [4]. This was felt to be caused by the way in which important signs of distress were often the absence of signs of contentment. Different cues were picked up by different carers, probably as a result of the diverse relationships each had with the patient. Hence, involving several carers to generate the DisDAT documentation produces a more complete picture of the person's behaviours of distress. The tool is not designed to be a scoring tool. A change in behaviour, however, can be monitored using monitoring sheets based on the PACA scoring system [203]. A specific score is not linked to a level of distress as different patients will generate differing numbers of distress cues. The scoring system is designed to monitor change once distress has been identified and a treatment put in place. Regnard *et al* also emphasise that the context in which the distress occurs is critical in identifying its cause.

Although DisDAT was not designed to be used in elderly patients with severe dementia, its flexibility in generating behaviours unique to the individual means that it could be used in this group. There is a lack of psychometric data regarding DisDAT; this is being addressed by on-going validity studies. The tool is also currently being evaluated in general hospital care. The tool allows for subtle unique behaviours to be identified so that more unusual presentations of distress are not overlooked. This allows a more individualised approach to pain management to be adopted as recommended by numerous

authors [169, 204, 205]. The importance of knowing the person well and therefore being able accurately to interpret behaviours has been recommended by several authors including Closs *et al* [205]. The DisDAT tool allows the great experience of the carers of the patient to be distilled into a document allowing their knowledge to be used by those new to the patient. In these ways the DisDAT tool provides a potential remedy to the concerns raised regarding current published pain and discomfort tools and hence is the second assessment tool used in the study.

### **1.5 The management of pain in dementia**

Once pain has been identified a variety of pharmacological and non-pharmacological methods can be used to treat it. Pharmacotherapy is commonly used to control pain and all treatments carry a balance of benefits and risks. As no two patients will respond to the same degree or experience side effects to the same drug, any intervention has to be individually tailored to the patient's needs [123]. As discussed previously, the elderly are particularly susceptible to drug side effects, and adverse drug reactions occur more frequently than in younger patients. The alterations in pharmacokinetics and pharmacodynamics seen in the elderly lead to varying oral bioavailability, differing drug distribution, changes in metabolic clearance and differing end organ responses to drugs [206]. These issues can lead to an increased frequency of constipation, confusion and orthostatic hypotension owing to drug treatments [112].

The majority of trials of pharmacological agents have been carried out in young or middle aged adults, not in older people [28]. These factors need to be carefully borne in mind when prescribing any drug, not just analgesics, for this group. Hence a sensible approach is to start with the lowest anticipated effective dose, monitor frequently on the basis of expected absorption and known pharmacokinetics of the agent and then titrate the dose on the basis of likely steady state blood levels and clinically demonstrated effects [123]. Using drugs with a short half life may be useful initially as the elderly are particularly susceptible to drug accumulation [207]. Using a combination of pharmacological and non-pharmacological techniques often results in more effective pain control and less reliance on medications that have major side effects in elderly patients

[28]. There have been no specific studies on the metabolism of analgesics in older people with dementia, so the current knowledge is based on the principles of using analgesics in all elderly people [124].

Evaluating the underlying nature of the pain is important as this will govern its treatment. The mechanisms underlying pain are often divided into the categories of nociceptive and neuropathic pain [114]. Nociceptive pain results from direct stimulation of pain receptors and arises from inflammation, tissue injury or mechanical deformity. This type of pain often responds well to the analgesics that form the WHO analgesic ladder. Neuropathic pain results from injury to nerve fibres from compression, infiltration or degeneration of neurons. Although neuropathic pain may respond to the analgesics of the WHO ladder, it also responds to adjuvant agents such as antidepressants or anticonvulsants. Some pains may have both nociceptive and neuropathic elements.

The principles governing analgesic use have been encapsulated in a series of slogans by the WHO [17, 208]. Drugs should be given by mouth where possible, by the clock and by the ladder, using a three-step analgesic ladder. Prescribing drugs on an “as required” basis partly requires the individuals to request medication. Many people with cognitive impairment are often unable to initiate a request for analgesia even if they can report pain when asked directly. This may therefore lead to under-treatment of pain in those with cognitive impairment [209]. The first step of the analgesic ladder is the prescription of non opioid drugs such as paracetamol and NSAIDs, followed by adding weak opioids as step 2 and then step 3 is the prescription of strong opioids with non opioids. Adjuvant



analgesics (neuropathic agents, psychotropic medication) can be added at any step. Drug treatments move up the ladder if an optimal dose of the drug fails to give adequate relief. This framework can be applied to the pharmacological treatment of pain in the elderly.

## **1.5.1 Pharmacological management of pain**

### **1.5.1.1 Paracetamol**

Paracetamol is often the first choice for musculoskeletal pain in elderly patients [28, 123, 210]. The maximum recommended dose for patients with normal renal and hepatic function or history of alcohol abuse is 4g a day. In those with renal or hepatic function, dose reduction by 50-75% is recommended [123]. Care needs to be taken to avoid the concomitant prescription of paracetamol and combination drugs containing paracetamol as this can potentially lead to liver toxicity [210]. Paracetamol is available in liquid and soluble form which can be easier for those with swallowing difficulties to take. However, the lack of a slow release preparation means administering the drug four times a day which may be difficult for some patients. The small incidence of drug interactions and lack of gastrointestinal side effects [125] lead to paracetamol being frequently prescribed for elderly patients with pain.

### **1.5.1.2 Non Steroidal Anti-inflammatory Drugs (NSAIDs)**

NSAIDs can also be used for musculoskeletal pain; however the side effect profile of this group of drugs means that they are less safe to use. All NSAIDs can cause peptic ulcer disease, renal failure and fluid retention [211] and these effects are more pronounced in

elderly patients owing to the changes in pharmacokinetics and dynamics as outlined above. NSAIDs vary in their selectivity for inhibiting different types of cyclo-oxygenase: selective inhibition of cyclo-oxygenase-2 improves gastrointestinal tolerance. Cyclo-oxygenase-2 selective inhibitors (such as celecoxib and rofecoxib) were hoped to have a better safety profile [210], however emerging concerns regarding cardiovascular safety suggests these drugs should be avoided in those with ischaemic heart disease or cerebrovascular disease [211]. Ibuprofen has fewer side effects than other non selective NSAIDs; however its anti-inflammatory properties are weaker. Hence paracetamol may be the preferred choice of non opioid analgesic, with NSAIDs used with caution and co-prescribed with a proton pump inhibitor or misoprostol because of the high incidence of gastrointestinal toxicity [212]. The American Geriatric Society suggests that NSAIDs should be avoided in those needing long term daily analgesic therapy.

### **1.5.1.3 Weak opioids**

The main weak opioids prescribed in the UK are codeine, dihydrocodeine and tramadol. The division between weak and strong opioids is arbitrary, as by injection most weak opioids can provide analgesia approximately equivalent to morphine 10 mg [208]. Codeine is partly a prodrug of morphine, hence many of the issues surrounding its prescription are similar to other opiates. It is worth noting that 10% of the population cannot convert codeine to morphine and hence may not derive analgesic benefit from it. Dihydrocodeine can be used alone or with paracetamol; it has an active metabolite dihydromorphine. Tramadol forms a bridge between classic weak and the classic strong opioids. It has a dual mechanism of action binding to opioid receptors and inhibiting

noradrenaline and 5HT reuptake. Its efficacy and safety are reported to be similar to equianalgesic doses of codeine including the potential for drowsiness and nausea [123]. There is some evidence that it can lower seizure threshold, so should be used with caution in those with epilepsy and in those taking other medication that can lower seizure threshold [123, 208].

#### **1.5.1.4 Opioids**

Strong opioids form the third step of the WHO pain ladder. There are often misconceptions surrounding the use of this group of drugs with beliefs that they are a last resort treatment and that patients will become addicted to them. True addiction in older patients with persistent pain syndromes is rare in comparison with the known prevalence of untreated debilitating pain. Longitudinal studies suggest that tolerance is slow to develop in the face of stable disease [123]. There is no ceiling to their analgesic effect but dose is often limited by side effects [213]. Caution must be taken when prescribing opiates on account of age related changes in renal function leading to accumulation of glucuronide metabolites [124]. In addition,  $\mu$ -Opioid receptor densities decrease with age; this is accompanied by an increase in receptor affinity [113]. Advanced age is also associated with a prolonged serum half life for most opiate drugs. Hence, for a variety of reasons, pain relief may be achieved with smaller doses than might be expected [28]. Serious side effects such as impaired consciousness or respiratory depression are rare, especially when doses are started low and escalated slowly, allowing for steady state blood levels to be reached at each dose prescribed [123]. This approach allows for the variability in drug effects that can be seen in older people treated with opioids because of

the factors described above. The potential to develop opiate related side effects such as constipation and nausea are increased, hence prescribing appropriate laxatives and anti-emetics, where needed, is important.

Morphine remains the first line choice of opiate in the UK; however oxycodone, fentanyl and hydromorphone are also prescribed [214]. Many opiates can be given as slow release preparations and it is vital that these drugs are not crushed to allow ease of swallowing [210]. Fentanyl patches are sometimes used for patients with swallowing difficulties, however their use can be problematic in older people owing to the lipophilic nature of the drug and changes seen in fat stores compared to younger patients [215]. The drug forms a reservoir on account of the transdermal delivery and hence has a long serum half life [28]. The drug is therefore not recommended for use in opiate naïve patients and should be used with caution if switching from a different opiate to fentanyl patches. Opiates can also be given subcutaneously via a syringe driver which can be beneficial if pain control is needed in patients unable to take oral preparations. Although some opioids are available as suppositories, this is likely to be unacceptable for long term use.

#### **1.5.1.5 Adjuvant analgesia**

Adjuvant analgesics can also be used at any stage of the WHO pain ladder. Neuropathic pain is often poorly controlled by opioids alone and the addition of antiepileptic and antidepressant drugs is often beneficial. Low dose amitriptyline can be used but anticholinergic side effects, orthostatic hypotension and the risk of arrhythmias may limit its use [144]. Carbamazepine and gabapentin can be used but starting at lower doses and

slowly increasing [210]. Capsaicin cream is a topical agent derived from cayenne pepper which acts by depleting nerve terminals of substance P, responsible for pain transmission [125]. It can be used for neuropathic pain; however the burning sensation that can occur with initial treatments may be intolerable to some patients [28]. Corticosteroids can also be used for cancer related nerve injury pain as a short term trial [208]. Antispasmodics can also be used for smooth muscle spasm but have anticholinergic side effects and can cause confusion in older people [211]. Benzodiazepines can be used to reduce anxiety associated with pain as well as relieving painful muscle spasm. The principles for prescribing any of these drugs are the same as for analgesics; start at low dose, carefully monitor for side effects, and increase the doses slowly allowing for steady state blood levels to be attained [123].

### **1.5.2 Non-pharmacological management of pain**

Non-pharmacological pain management strategies are often very effective when used in combination with drug strategies [28]. Physical methods, such as heat (stimulating production of endogenous opioids) and cold (suppressing the release of products from tissue damage), can be effective [210]. Massage has been shown not only to reduce pain scores [216], but also to reduce anxiety, agitation and other dysfunctional behaviour [217, 218]. Transcutaneous Electrical Nerve stimulation (TENS) and acupuncture are thought to cause endogenous opioid release, however it is debatable how well these approaches may be tolerated by those with severe dementia. Nerve blocks and tumour site radiation can be used for specific indications [210]. Other non-pharmacological approaches such as Cognitive Behavioural Therapy (CBT) have been recommended for use with older people

[123, 219], but are inappropriate for use with those with very severe cognitive impairments.

### **1.5.3 Prevention of pain**

It would seem sensible that as well as treating pain as it is recognised, that efforts should be made to prevent painful conditions occurring. Gentle exercise may help reduce immobility and inactivity that can worsen pain [28, 123, 210], as well as improving psychological wellbeing [144]. The frequency of fractures in the elderly can be reduced by preventing falls occurring in the first place and by using hip protectors and treating osteoporosis [206]. In addition, preventing painful pressure ulcers from developing by the use of pressure relieving aids, frequent turning and maintaining adequate nutrition is also important [206].

### **1.5.4 Alternative approaches to managing pain**

Although identifying pain using assessment tools would seem a logical approach to managing pain in those with severe dementia, several studies have used different methods. One such approach is to give all patients an analgesic to see if this improves difficult behaviour.

Chibnall *et al* [220] hypothesised that routine administration of an analgesic would increase social and physical activity, decrease agitation, increase emotional well-being and decrease the number of doses of as needed psychotropic medications in nursing home residents with moderate to severe dementia. A randomised, double blind placebo

controlled crossover trial was carried out in 25 residents who had a Functional Assessment Staging stage of five or six. Participants were given paracetamol 500mg three times a day for four weeks and a placebo three times a day for four weeks with a one week wash out period. There were multiple exclusion criteria including liver or renal compromise, anaemia, bedridden/comatose state, current routine prescription for paracetamol or an opioid and unstable medical disease that could interfere with participation. It was found that although there were some changes in observed behaviour (increased social interaction and activity levels) there was no decrease in agitation, no improvement in emotional well-being and no reduction in the number of PRN psychotropic medications. The results from this study are not only inconclusive (the authors felt that this may be due to their sample having low pre-intervention CMAI scores and low as required psychotropic medication use), but because of the multiple exclusion criteria it is also difficult to apply these results to a general nursing home population.

Similar work was carried out by Buffum *et al* [221] who gave 650mg paracetamol four times a day with PRN placebo for two weeks followed by placebo four times a day with PRN paracetamol to 39 nursing home residents with severe dementia. Levels of discomfort were monitored using the DS-DAT. No significant difference was noted in discomfort scores during either part of the trial, with few PRN doses being administered during the four weeks. It is possible that the behaviours documented using the DS-DAT were not due to pain, or that the paracetamol was inadequate to treat the pain.

A smaller study was carried out by Douzijan *et al* [222] who gave 650mg of paracetamol three times daily to ten residents with difficult behaviour who were also on psychotropic medication. Out of the eight subjects who commenced regular analgesia, five showed a decrease in behavioural symptoms. There was also a reduction in psychotropic and antidepressant drug prescribing. The number of participants in the study was too small to draw any major conclusions and it is not known what constituted a significant decrease in the assessment tool. Another problem with these studies is that paracetamol (particularly given at what seems to be sub therapeutic doses) may not have been adequate to control the participants' pain and hence reduce agitation.

A different analgesic was used in the study by Manfredi *et al* [223]. This group carried out a double blind placebo controlled cross over trial using placebo for four weeks and a long acting opioid (oxycodone 10mg twice daily) for four weeks with laxatives also given in the opioid phase. This was given to 47 nursing home patients with a MMSE of < 21 with persistent agitation (measured as a CMAI score of > 40) who were unable to complain of pain or did not suffer from a painful condition. Again there were multiple exclusion criteria including liver and renal compromise, constipation, hypoxia, hypotension and those already on opioids. Oxygen saturation, respiratory rate and sedation (using the Ramsey Sedation scale) were monitored and the CMAI score was recorded every two weeks.

Only 25 participants completed the study (discontinuation reasons included unsteady gait, increased agitation and faecal impaction) and there were no significant differences in



agitation scores between the placebo and opioid phases. The authors claimed that the levels of various adverse events (constipation, falls and nausea) were not statistically different in the two treatment phases; however it is possible that these events were reasons for withdrawing from the study. In addition it is not clear how nausea was monitored as the participants were unable to communicate that they had pain. Agitation levels were significantly lower after the opioid phase in 13 of the subjects who were over 85, after adjusting for sedation level. The actual opioid used varied in the study as 12 of the subjects could not swallow tablets. These participants were given 20mg of long acting liquid morphine instead, however this is not equivalent to the oxycodone dose (which should be 30-40mg morphine). The authors concluded that treatment with low dose, long acting opioids is safe in agitated elderly demented patients. This study is clearly flawed on many levels with multiple exclusion criteria, a high drop out rate, different and not equivalent opioids used and no difference in agitation levels seen in those that completed the study, other than when the study group was divided arbitrarily by age.

None of these studies provides good evidence for the blanket prescribing of analgesics for elderly demented patients in an attempt to reduce agitation. Although agitation may well be caused by undetected pain, prescribing analgesics to all without any other form of assessment can lead to sub therapeutic-treatment of pain in those with pain and unnecessary additional medication for those without.

## **1.6 Conclusions**

The review of the current literature has demonstrated that the principles of palliative care apply to those with severe dementia. This includes addressing several important issues including physical symptoms, end of life care and providing psychological, social and spiritual care. The difficulties in assessing pain in dementia have been highlighted, with the evidence regarding under-recognition of pain in this group discussed. The use of behavioural assessment tools to identify pain has been debated, yet it remains unclear how useful such tools are in assessing pain. Concerns have been raised that pain assessment tools may not solely identify pain. Understanding how frequently this may occur and what the cause of the behaviour observed might be will further the understanding surrounding the use of pain assessment tools. Although the principles of managing pain in patients with severe dementia have been identified, putting these principles into practice is important.

Hence the aim of the research is:

To demonstrate the importance of assessing and managing pain as part of good quality palliative care in people with severe dementia.

And the objectives of the research are:

1. To investigate the utility of a pain assessment tool and a distress assessment tool in a UK population with severe dementia; to test the hypotheses that a) pain is common and under-recognised in this population and b) that such tools can reliably be used to identify pain;
2. To demonstrate the ability of the tools to measure change in pain following a change to the management regime; to test the hypothesis that the tools are sensitive to change;
3. To assess the nature of distress that may produce a false positive result on a pain scale; to test the hypothesis that pain tools will identify behaviour owing to a variety of causes;
4. To examine the use of analgesia within the nursing homes and in those identified as experiencing pain; to test the hypotheses that a) analgesics may be prescribed inadequately for those with dementia and b) pain can be managed using both simple pharmacological and non-pharmacological techniques.

## **Chapter 2 ~ METHODS**

### **2.1 Protocols and Procedures**

The research has been carried out in one continuing care NHS unit for people with severe dementia (i.e. elderly severely mentally impaired (ESMI) unit) and three privately run elderly mentally infirm (EMI) nursing homes in the North Tyneside area. Ethical committee approval was sought and obtained from the local research ethics committee of Newcastle and North Tyneside. Research governance approval was also sought and obtained from the Research and Development department of Northumbria NHS Trust. Caldicott approval was gained to review medical and psychiatric notes held within the trust.

#### **2.1.1 Inclusion and exclusion criteria**

All people entering the study had an established clinical diagnosis of dementia and had advanced disease (i.e. Clinical Dementia Rating score of three [134, 135]). They were unable to communicate verbally in a reliable or consistent manner and were residents in long-term care facilities. There were no specific exclusion criteria.

#### **2.1.2 Research stages**

##### **2.1.2.1 Stage 1**

Contact was made with nursing homes, identified by members of the North Tyneside Old Age Psychiatry team, known to have large numbers of residents with severe dementia.

The project was discussed initially with the home management team and information regarding the research project was provided. Once the home manager was agreeable, the project was explained to as many staff as possible. If the home had a relatives group then the project was presented to this group as well. Two of the homes were run by Southern Cross Healthcare, an independent provider of nursing care services, information was sent to the ethics committee of this company.

Potential participants were identified with the help of the home staff by completing a Clinical Dementia Rating scale on all residents within the home. All residents with a CDR of three were randomly assigned a number with a prefix to identify the home in which they lived (TC Tynemouth Court, WC Willow Court, CP Cleveland Park, AP Appleby nursing home). This number was used to identify the participant with any data held pertaining to them. Information regarding the participants' identity and the assigned codes was kept separate from study data. The next of kin of all suitable residents were then sent a letter regarding the study with an information sheet. Telephone contact was made with the next of kin to arrange a meeting for further discussion of the research and to sign an assent form. If there was no next of kin, the solicitor acting as next of kin was also contacted to see if assent could be given. The General Practitioners of all those participating were also contacted to inform them that the person was included in the project. It was made clear on the information sheet and in the assent procedure that the next of kin were free to withdraw their assent at any time and for whatever reason.

The patient's nursing, medical and psychiatric notes were reviewed prior to the study commencing. If there were no medical or psychiatric notes held by North Tyneside General Hospital then the participants' GP notes were reviewed. The notes were reviewed in order to:-

- (a) Confirm the inclusion criteria were satisfied (that the diagnosis of dementia subtype fulfilled the DSM IV classification [224] or for DLB, fulfilled the consensus guidelines for the diagnosis of dementia with Lewy bodies [225]);
- (b) Note basic demographic details such as age, date of admission to current home and ethnicity;
- (c) Record past medical history particularly co-morbidities that could potentially be painful;
- (d) Record dementia type and date of diagnosis;
- (e) Record all prescribed medication at the commencement of the study.

The information from the notes review was documented on a data recording sheet with only the assigned number for identification. The data sheet information was transferred to a password secured trust computer and the data sheets were stored in a locked filing cabinet.

Several neuropsychological scales were also completed for each participant by the nursing staff. These were the Cornell Scale for Depression in Dementia (CSDD) [226], Clifton Assessment Procedure for the Elderly – Behaviour Rating Scale (CAPE-BRS)

[227], Neuropsychiatric Inventory (NPI) [228] and the Cohen-Mansfield Agitation Inventory (CMAI) [148]. The scores for each assessment were entered onto a separate score sheet, entered into the database and stored with the data recording sheets.

In addition, the Disability Distress Assessment Tool (DisDAT) [4] was completed for the particular participant in conjunction with both nursing staff and relatives where possible. The number of distress behaviours for each participant was noted, as well as the frequency of the documented behaviours. Appropriate training was given to the nursing staff regarding completion of the PAINAD and DisDAT tools.

#### **2.1.2.2 Stage 2**

All the participants in the study were observed on three occasions for approximately 5 minutes by the researcher and a nurse from the home:-

- (a) At a time of rest
- (b) At a meal time
- (c) At a time of intervention.

These three times for observation were chosen as they would occur each day for each participant. In addition it was felt that the different observations might provide different information about any pain that might be experienced; for example, behaviours caused by musculoskeletal pain would be more likely to be observed during intervention than at rest. The observation at rest was usually carried out during the afternoon whilst the

residents were sitting in the lounge, the meal time used was usually lunchtime and the intervention observation was usually carried out when the participant was got out of bed in the mornings. Occasionally it was difficult to carry of the observation at these times so different observation timings were used, having discussed matters with the nursing staff to determine the most suitable time. If this occurred, the same observation timings for that participant were used at the repeat observations. At each of these three times, the researcher completed one of the tools (i.e. PAINAD or DisDAT) and the nurse from the home independently completed the other tool. The researcher completed the PAINAD for those with even assigned code numbers and the DisDAT for those with odd numbers. The nurse completed the PAINAD for those with odd assigned code numbers and the DisDAT for those with even numbers. This was to ensure that the person completing the specific tool was allocated randomly as the code numbers had been assigned at random. The researcher and the nurse did not confer during the completion of the scales. Once the tools were completed, the cause of the behaviour seen was discussed to determine whether it was felt to be caused by pain or whether it had some other cause. The researcher also made notes to assist in deciding whether the behaviours observed were caused by pain or were due to another cause. The participant was examined if this was appropriate. If it remained difficult to ascertain the cause of the behaviours seen, the observation was repeated and other staff members or medical professionals consulted.

In summary, the decision about whether or not a participant's behaviour indicated the presence of pain was determined by:-



- a) A review of medical, psychiatric and nursing notes;
- b) Information gleaned from discussion with relatives during the assent procedure;
- c) Observations by a doctor specialising in palliative medicine and a nurse familiar with the patient on three occasions using two different observational tools;
- d) A discussion after the observations between the doctor and the nurse;
- e) A physical examination if necessary and appropriate;
- f) Repeated observations if necessary;
- g) Further discussion with other nursing and medical professionals if necessary.

All participants who were assessed as being in pain continued into stage 3 of the protocol (P group). Those who were not assessed as being in pain but had scored significantly on the PAINAD scale (a score greater than 2) also continued into stage 3 (FP group). Those who were not felt to be in pain and had not scored significantly on the PAINAD scale (a score equal to or less than 2) left the research at this point (NP group). The reasons for using two as a cut off score are discussed in section 2.2.4 of this chapter.

A second researcher also carried out the observations using the same assessment scale as the researcher within a week of the original observations to provide evidence of inter-rater reliability. Two researchers carried out these observations, Dr Sarah Hepburn and Dr Mani Bhasin, both experienced Specialist Registrars in Psychiatry of Old Age. Appropriate training was given to both second researchers regarding the completion of the PAINAD and DisDAT tools.

### **2.1.2.3 Stage 3**

A decision was made for those participants in the P group with regards to management of the pain. This was made by the researcher in conjunction with the nursing home staff as well as the GP where necessary. If the decision required input outside the experience of the researcher, an appropriate opinion was sought. If the decision required a change in medication this was made in agreement with the GP and the GP kept informed by letter of the results of further observations. A discussion took place with the nursing staff as to the likely cause of distress of those in the FP group. Any potential alleviating measures for the observed distress were also discussed.

### **2.1.2.4 Stage 4**

Clinical re-assessment by the researcher occurred weekly to monitor the effects of any treatment suggested. At approximately one month, the participants in the P group and the FP group were re-assessed using both the DisDAT and PAINAD, again in three different circumstances, and again by a nurse from the home and the researcher scoring the same instruments as before. At this stage the CSDD, CAPE, NPI and CMAI scales were repeated.

### **2.1.2.5 Stage 5**

At three months from the original assessment there was further re-assessment of both the P and FP groups using DisDAT and PAINAD. This was again in three different circumstances and again by a nurse from the home and the researcher scoring the same instruments as before. In addition a further review of notes and medication took place

order to account for any changes in the participant's clinical state. If at that time there was evidence of on-going pain, this was referred back to the participant's GP.

## **2.2 Scales used in the research**

### **2.2.1 DSM IV Classification**

The DSM IV Classification [224] is a categorical classification that divides mental disorders into types based on criteria sets with defining features. It was used to verify that the criteria had been met for the diagnosis of dementia and for the type of dementia diagnosed. For DLB, the only common type of dementia which is absent from DSM, the consensus guidelines for the clinical and pathological diagnosis of dementia with Lewy bodies was used [225].

### **2.2.2 The Clinical Dementia Rating Scale (CDR)**

The CDR [134, 135] gives a global measure of dementia assessing six domains: memory, orientation, judgement and problem solving, community affairs, home and hobbies and personal care. The total CDR rating is made from the sum of boxes which represents an aggregate score of each individual's areas. CDR ratings are zero for healthy people, 0.5 for questionable dementia and 1, 2, and 3 for mild, moderate and severe dementia (Appendix p315)

## **2.2.3 Background neuropsychiatric scales**

### **2.2.3.1 The Cornell Scale for Depression in Dementia (CSDD)**

The CSDD [226] (Appendix p321) is specifically designed to assess signs and symptoms of major depression in patients with dementia. The 19 item scale is rated on a three point score of absent, mild/intermittent and severe. The item scores are added; those above 10 indicate a probable major depression, above 18 definite major depression and below 6 as associated with absence of significant depressive symptoms. The CSDD can be completed using both informant interview and patient interview. In the current research, informant interview was used.

### **2.2.3.2 The Clifton Assessment Procedure for the Elderly – Behaviour Rating Scale (CAPE-BRS)**

The CAPE-BRS [227] (Appendix p318) assesses mental and physical functioning in elderly people by recording physical disability, apathy, communication difficulties and social disturbance. It consists of 18 statements, each with three possible answers scoring zero, one or two. The score can be equated to a dependency grade indicating the level of care that may be required.

### **2.2.3.3 The Neuropsychiatric Inventory (NPI)**

The NPI [228] (Appendix p322) evaluates psychopathology by assessing 12 behavioural areas including delusions, hallucinations and anxiety from informant interview. Each

domain is rated in terms of frequency (from 1 to 4) and severity (1 to 3). These numbers are multiplied to give the score; hence the maximum score is 144.

#### **2.2.3.4 The Cohen-Mansfield Agitation Inventory (CMAI)**

The CMAI [148] (Appendix p320) looks at agitated behaviour in patients with cognitive impairment. It consists of 29 behaviours, with each rated by an informant using a 7 point scale according to frequency in the previous 2 weeks. The minimum score is 29, maximum score is 203.

#### **2.2.4 The Pain Assessment in Advanced Dementia (PAINAD) Scale**

The PAINAD [3] (Appendix p324) has been designed as a simple, valid and reliable instrument for the measurement of pain in non-communicative patients. It is a five item observational tool that is scored from 0 to 10. As discussed in chapter 1, PAINAD is based on categories and behaviours from the Face, Legs, Activity, Cry, Consolability scale (FLACC) [193], Discomfort Scale for Dementia of the Alzheimer Type (DS-DAT) [52] as well as on a literature review and consultation by experts in the field. Since publication, several research studies have used PAINAD to evaluate pain providing further information on its psychometric properties and utility in those with severe dementia [118, 183, 196, 198, 200-202, 229]. The original research paper [3] does not give an indication of how to interpret the scores, but as the scale is designed to score from 0 to 10 to be comparable to severity scores, it was presumed that a higher score was designed to reflect more severe pain. Reviews of pain measurement [230] have suggested that a score of above 20mm on a 100mm scale is a useful cut off for relevant pain. In the

initial research, the mean PAINAD scores (+/- Standard Deviation) at a time of no stimulation were 1.3 (+/- 1.3), were 1.0 (+/- 1.3) during pleasant activity and 3.1 (+/- 1.7) during intervention. In addition, the study by Leong *et al* using PAINAD determined that a score of 0-1 corresponded to no pain, 2-3 to mild pain and a score of 4 and above would correspond to moderate and above pain [198]. Based on these results it was decided that a PAINAD score above 2 was likely to be significant and this therefore provided the level for the false positive (FP) group.

#### **2.2.5 The Disability Distress Assessment Tool (DisDAT)**

The DisDAT [4] (Appendix p327) is designed to help identify distress cues in people with limited communication (owing to cognitive impairment or physical illness). It is completed by those caring for the person, who compile lists of behaviours that they recognise as signs of contentment and distress. Documenting the behaviours is felt to increase carer confidence in their ability to pick up distress and facilitate the identification of underlying causes for the distress observed. The DisDAT is not a scoring tool, however change in behaviour can be monitored using monitoring sheets based on the PACA system [203] (Appendix p331). If the behaviour was absent during the observation it scored 0, if it was present it scored 1, if it moderately affected the observation it scored 2 and if it dominated the observation it scored 3. This system was used in the study to monitor change after treatment for pain was initiated.

## **2.3 Variables collected**

### **2.3.1 Analgesia**

All medication that the participants were prescribed was documented on commencement of the research by examining the current medication charts in the home. Although many participants were prescribed regular Aspirin, this was only included as analgesia if this was the reason for which it was prescribed. In fact most Aspirin prescriptions were for prevention of cardiovascular events. In a similar way any other drugs, such as antidepressants or anticonvulsants, that could be used as analgesics were not included unless they had been specifically prescribed for this reason. Three categories of analgesia were created, regular (including those prescribed regular analgesia as well as required analgesia), as required (for those only prescribed PRN analgesia) and none (for those not prescribed analgesia at all).

### **2.3.2 Diagnoses**

The participants' dementia diagnoses were documented from review of medical, psychiatric and GP records. Most participants had had the dementia diagnosis made by a Consultant Psychiatrist. However, if it was difficult to find evidence of review by old age psychiatry services, the DSM IV [224] classification was used to check that the diagnosis made was appropriate. The last recorded diagnosis was used as the dementia diagnosis since the type of dementia may not be apparent at the time of initial presentation. If the type of dementia was not documented, then the medical and psychiatric notes were reviewed by a consultant psychiatrist to give a likely dementia type on the basis of

documented evidence. If this was impossible to do, but the participant clearly had dementia, the type of dementia was categorised as not known (NK).

### **2.3.3 Length of time since diagnosis made**

This was recorded in months as the time since a formal diagnosis of dementia was made by a doctor or member of the old age psychiatric team (and documented in medical, psychiatric or GP records) to the date of consent being given.

### **2.3.4 Length of stay in home**

This was recorded in months as the time since the participant was admitted to their current place of residence (from the notes held in the nursing home) to the date of consent being given.



## **2.4 Statistical methods**

All the statistical methods were undertaken using SPSS-14. Normality of data was assessed using the Kolmogorov-Smirnov tests of normality, as well as examining histograms and normality curves. Results were determined to be significant if  $p < 0.05$ . All significant results are highlighted in red in the results section.

Owing to small expected frequencies of some of the variables, the associations between categorical data were analysed using Fisher's exact test. Where the data was normally distributed, the associations between categorical and numerical data were analysed using one way analysis of variance (ANOVA). If the numerical data was non-parametric in nature, the associations between this data and the categorical data was analysed using the Kruskal-Wallis test. Further analysis of statistically significant results from using the Kruskal-Wallis test were analysed using the Mann-Whitney Exact test.

The Wilcoxon signed ranks test was used to look at the paired observations of baseline and 1 month observations, 1 month and 3 month observations and the baseline and 1 month neuropsychological scores. This test was used as the difference between the scores was shown to be not normally distributed. Analysis of the proportion of change in the scores for each group was analysed utilising the Mann-Whitney test.

The correlations between numerical data were analysed using Spearman's Correlation Coefficient as the data was non-parametric in nature. The strength of the association was graded according to the scores shown below

*Table 2.1 Spearman's correlation coefficient and association strength*

<b>Correlation Coefficient (r)</b>	<b>Strength of association</b>
0 - 0.33	Weak
0.34 – 0.66	Moderate
0.67 – 1	Strong

(Adapted from Swinscow [231])

The degree of agreement between the researcher observation scores and the 2<sup>nd</sup> observer scores was analysed using the kappa statistic. Weighted kappa was used to take into account the extent to which the observers disagreed as well as the frequencies of agreement. The degree of the agreement was graded as shown below.

*Table 2.2 Kappa score and degree of agreement*

<b>Kappa score (<math>\kappa</math>)</b>	<b>Degree of agreement</b>
$\kappa \leq 0.20$	Poor
$0.21 \leq \kappa \leq 0.40$	Fair
$0.40 \leq \kappa \leq 0.61$	Moderate
$0.61 \leq \kappa \leq 0.80$	Substantial
$\kappa > 0.80$	Good

(Taken from Petrie and Sabin [232])

Figure 2.1 Flow chart of participants' experience

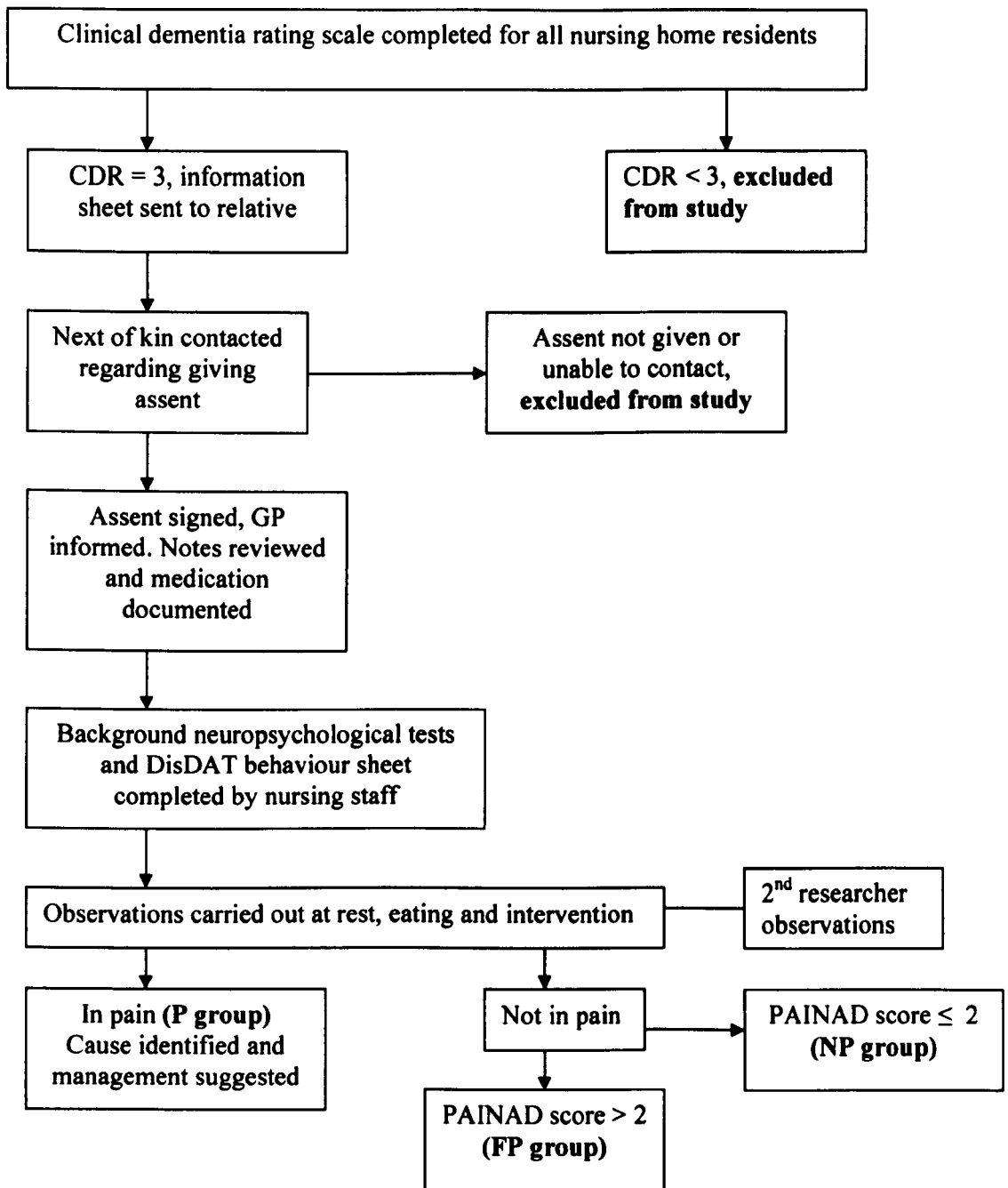
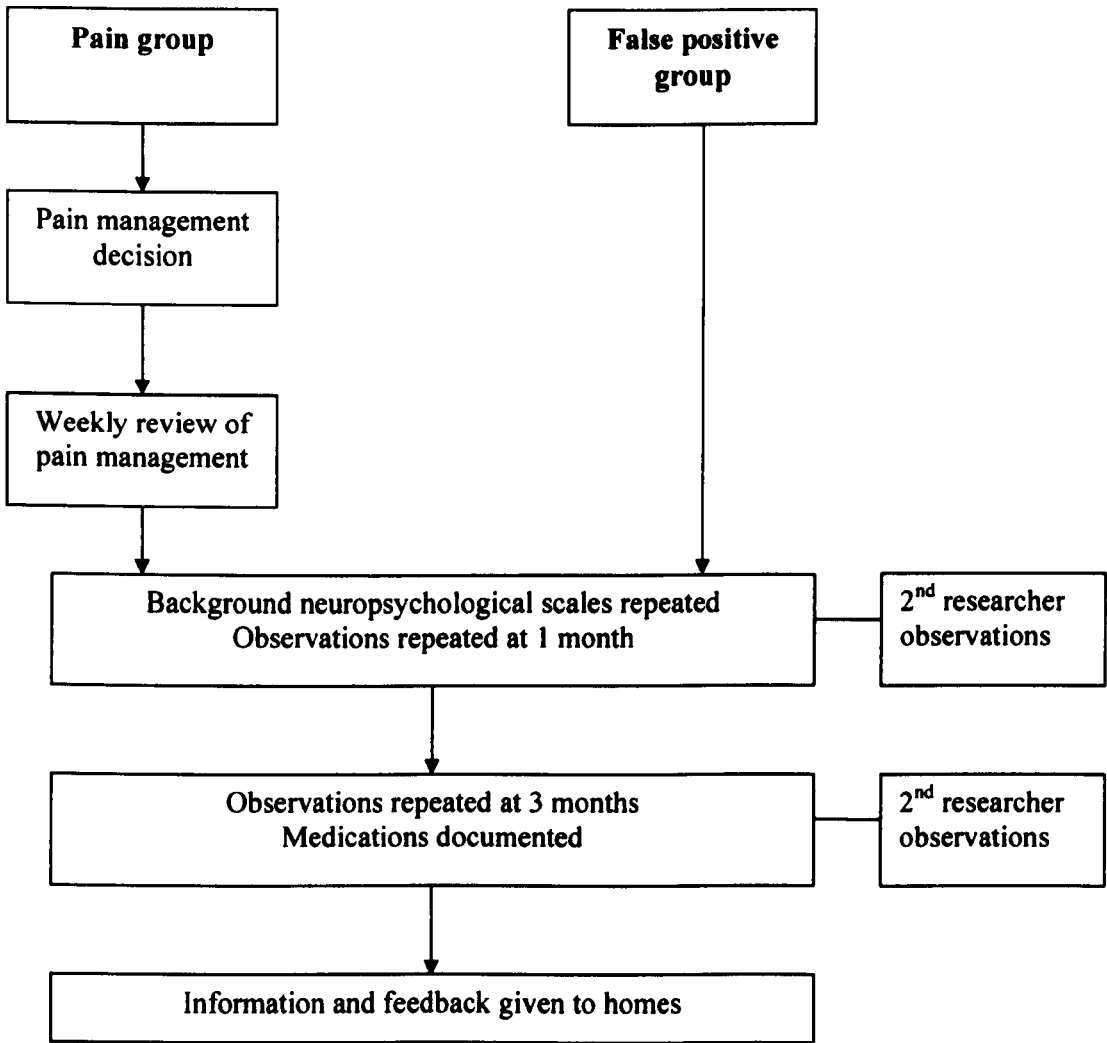


Figure 2.2 Management and assessment of the pain and false positive groups



## **Chapter 3 ~ RESULTS**

### **3.1 Background**

The data in this section provides background demographic information regarding the study participants.

#### **3.1.1 Patient selection**

Four homes in the North Tyneside region were approached to participate in the study and all agreed. The total number of residents in each home shown in the table below was the number of residents at the time of starting the research at each home. The total number of nursing home residents screened for the study was 192. From those screened for the study, 131 (68%) met the inclusion criteria and were therefore approached regarding the study. 61 residents had a CDR of less than 3 and were therefore excluded from the study.

Assent was gained for 79 of the remaining 131 residents, 60% of those who were approached. Whilst assent was being sought, 2 residents were transferred to other nursing homes and 9 residents died. Assent was not given for 41 potential participants; this was either due to the next of kin deciding against participating in the study (20 potential participants) or difficulties in contacting the next of kin (10 potential participants). The patients under the care of Dr. Hughes, a supervisor of the project, were excluded (6 potential participants). This was because of concerns that relatives might be unduly influenced to give consent. A further 5 potential participants had to be excluded as they did not have a living next of kin. Their appointed next of kin were contacted (all

solicitors) but none felt able to give assent for the research. Those next of kin who did not give assent were not asked specifically for the reasons why they had refused assent. The 52 potential participants for whom assent was not given, 58% were female and 42% were male. Assent was not withdrawn for any residents during the study, however a further 10 participants died between the initial assessments and the study completion. This process has been summarised in the table and figures below.

*Table 3.1 Outcomes of patient selection*

Home	No of residents in home	CDR 3	Died	Transferred	No Assent	Final no
Tynemouth Court	38	31	2	1	12	16
Willow Court	39	28	1	1	8	18
Cleveland Park	62	43	4	0	13	26
Appleby	53	29	2	0	8	19
<b>Total</b>	192	131	9	2	41	79

*Figure 3.1 Pie chart of outcomes of participants suitable for research*

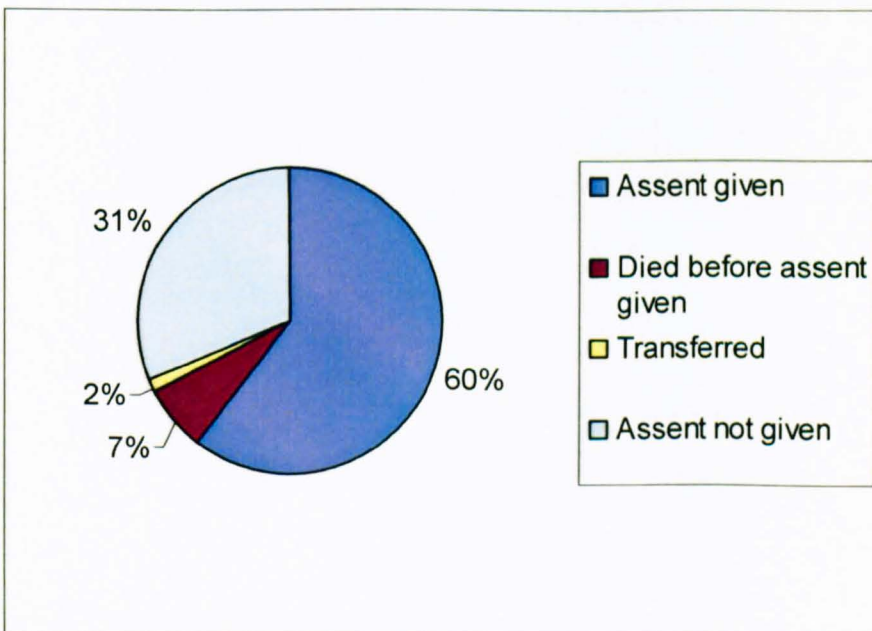
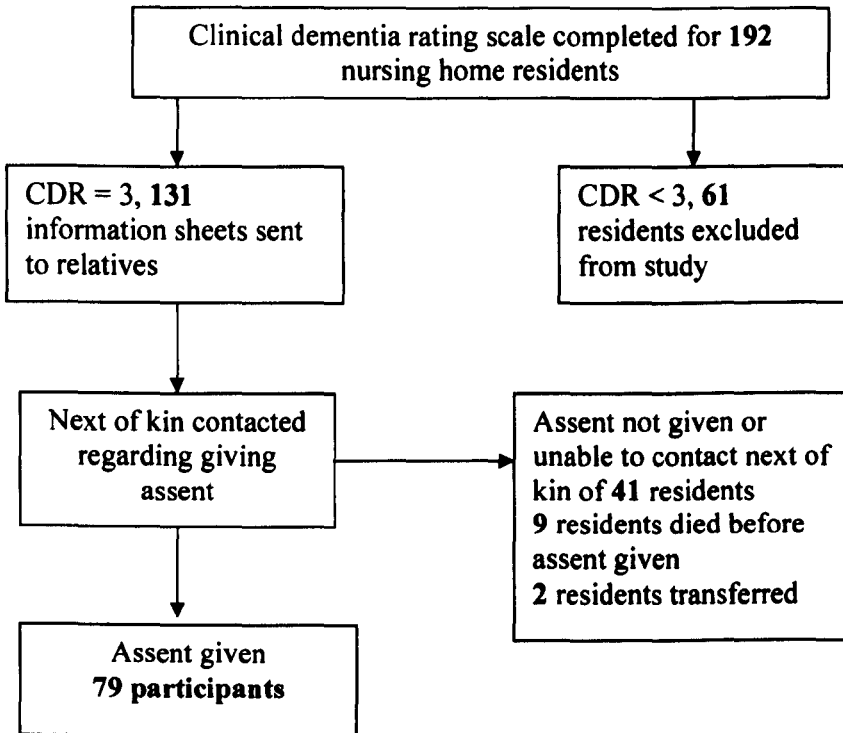


Figure 3.2 Flow chart of outcomes of patient selection



### 3.1.2 Sex

The gender of the study participants is outlined in the table below.

*Table 3.2 Gender of the study participants*

	<b>Female</b>	<b>Male</b>
<b>No of participants</b>	57	22
<b>Percentage of participants</b>	72%	28%

### 3.1.3 Diagnosis

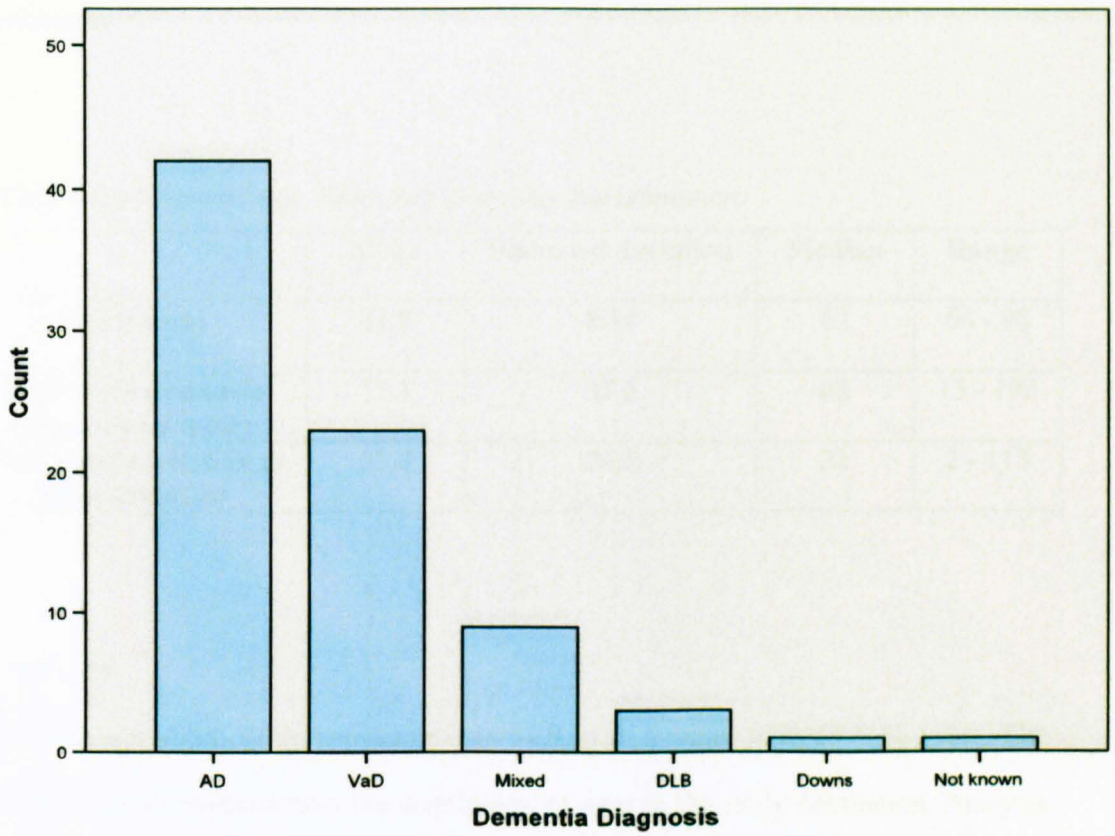
The dementia diagnoses, as ascertained by examination of the participants' medical notes, are documented in the table and histogram below.

*Table 3.3 Participants' dementia diagnoses*

	<b>AD</b>	<b>VaD</b>	<b>Mixed</b>	<b>DLB</b>	<b>Downs</b>	<b>Not known</b>
<b>No of participants</b>	42	23	9	3	1	1
<b>Percentage of participants</b>	53.2%	29.1%	11.4%	3.8%	1.3%	1.3%



Figure 3.3 Histogram of participants' dementia diagnoses



### 3.1.4 Age, time since diagnosis and time since admission to home

The table below summarises the other background variables collected on the study participants.

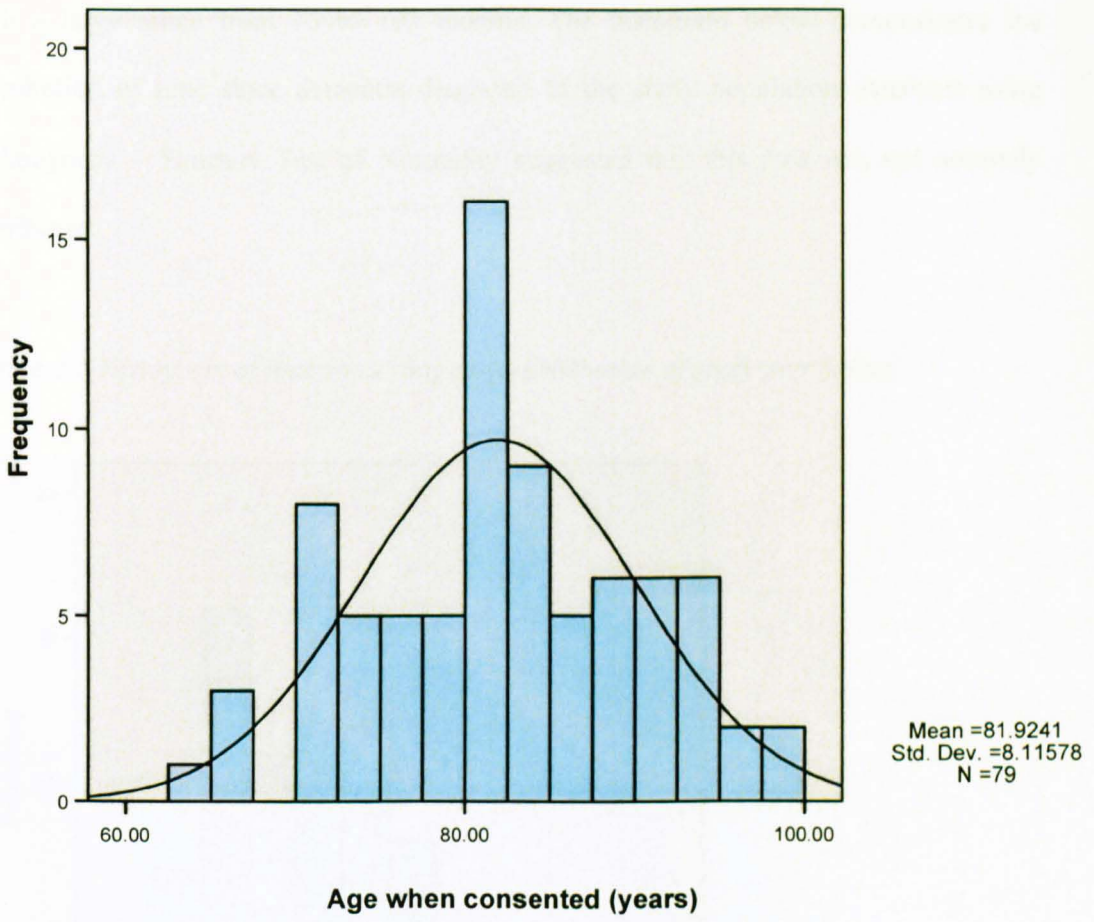
*Table 3.4 Participants' age, time since diagnosis and admission*

	<b>Mean</b>	<b>Standard deviation</b>	<b>Median</b>	<b>Range</b>
<b>Age (years)</b>	81.9	8.14	82	64 - 98
<b>Time since dementia diagnosis (months)</b>	71.1	35.2	68	15 - 192
<b>Time since admission to home (months)</b>	35.8	26.6	32	2 - 115

#### 3.1.4.1 Age

The mean age of the study population was 81.9, with a range from 64 – 98 years. The histogram below demonstrates the distribution of ages in the study population. Analysis using Kolmogorov – Smirnov Test of Normality suggested that this data was normally distributed.

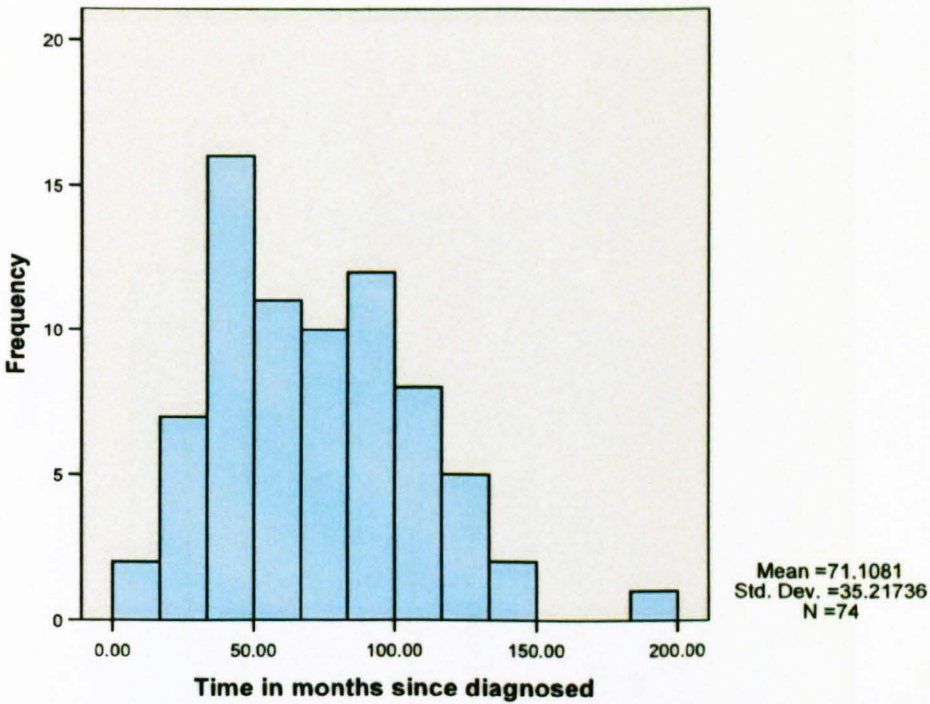
Figure 3.4 Histogram of age distribution of study population



### 3.1.4.2 Time since dementia diagnosis

The mean time, in months, since the diagnosis of dementia was formally made was 71.1, with a large range from 15 to 192 months. The histogram below demonstrates the distribution of time since dementia diagnosis in the study population. Analysis using Kolmogorov – Smirnov Test of Normality suggested that this data was not normally distributed.

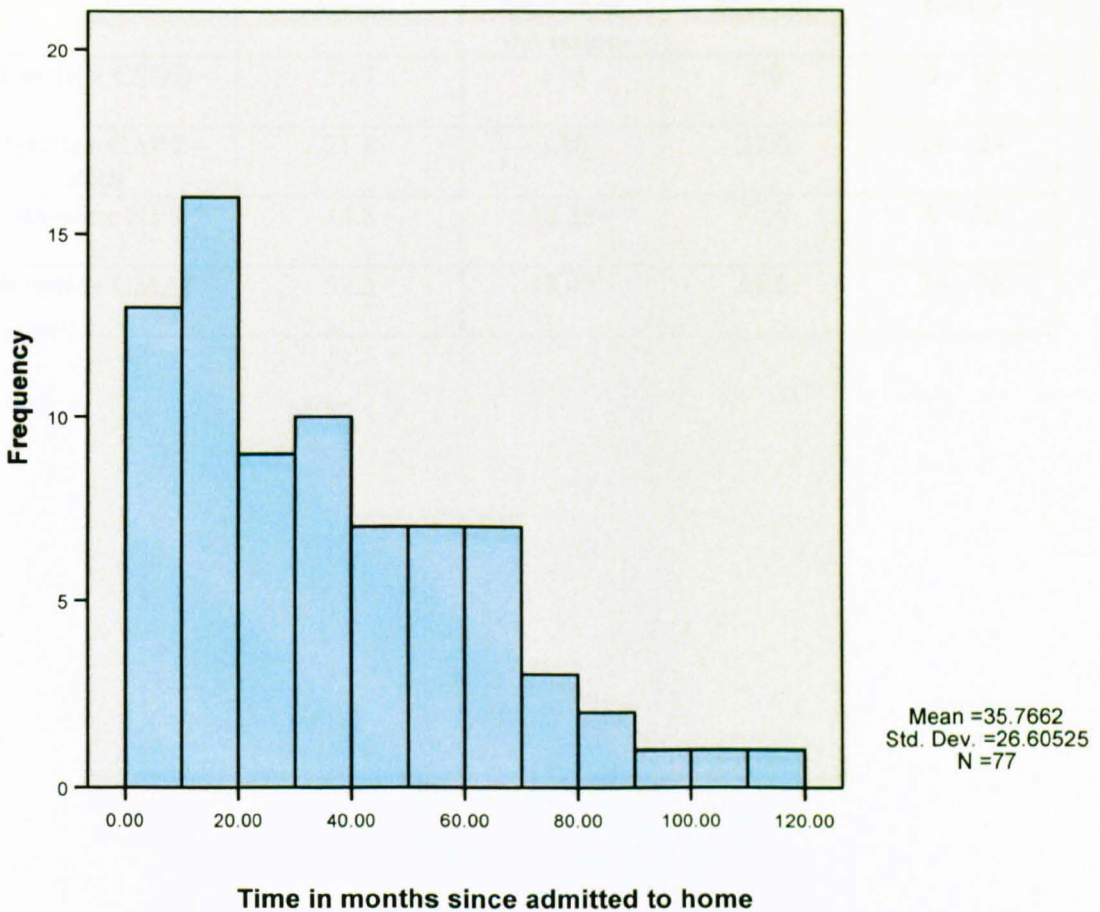
Figure 3.5 Histogram of time since diagnosis distribution of study population



### 3.1.4.3 Time since admission to home

The mean time since the participants had been admitted to their current nursing home was 35.8 months, again with a wide range of 2 to 115 months. The histogram below demonstrates the distribution of times since admission to home. The histogram is skewed to the left, with most participants having been in their current home for a shorter period of time.

Figure 3.6 Histogram of time since admission to current home



### 3.1.5 Background neuropsychiatric scales

In addition to the Clinical Dementia rating scale, all study participants had four neuropsychiatric tests completed. These were the Cornell Scale for Depression in Dementia (CSDD), Clifton Assessment Procedure for the Elderly – Behaviour Rating Scale (CAPE-BRS), Neuropsychiatric Inventory (NPI) and the Cohen-Mansfield Agitation Inventory (CMAI).

*Table 3.5 Background neuropsychiatric data*

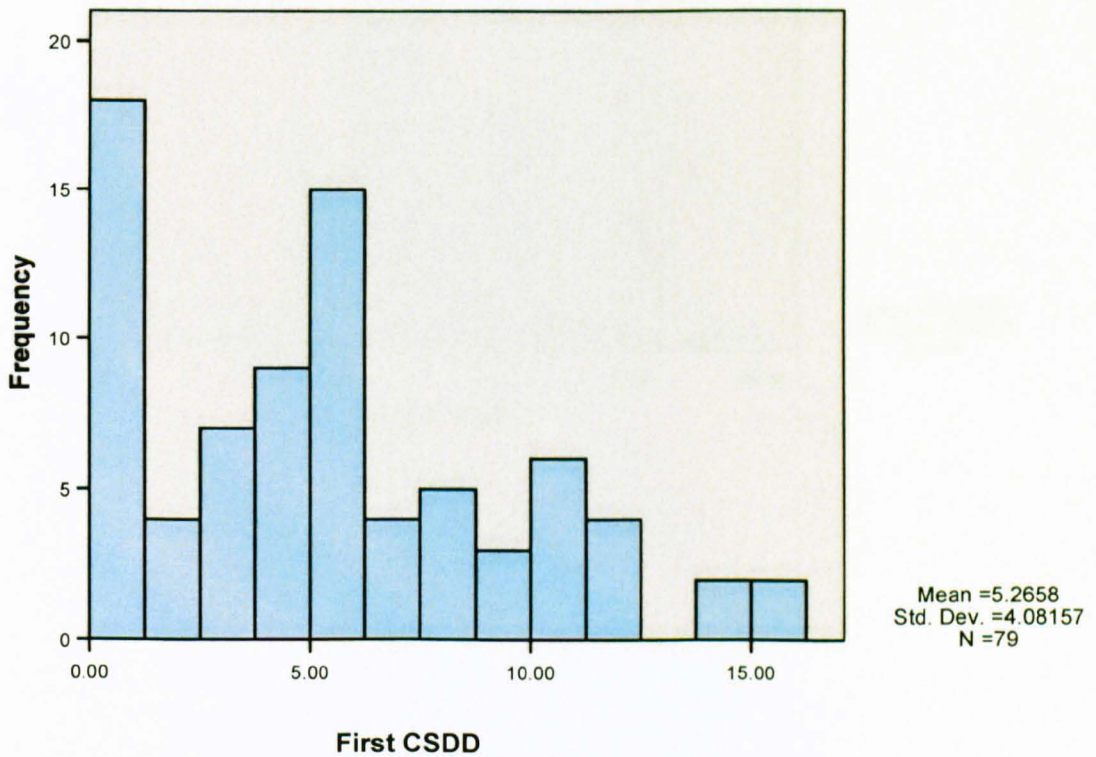
	<b>Mean</b>	<b>Standard deviation</b>	<b>Median</b>	<b>Range</b>
<b>Baseline CSDD</b>	5.27	4.08	5.0	0 – 16
<b>Baseline CAPE-BRS</b>	21.8	3.88	22.0	11 – 34
<b>Baseline NPI</b>	14.5	12.25	12.0	0 – 50
<b>Baseline CMAI</b>	52.2	18.45	50.0	29 - 96



### 3.1.5.1 Baseline CSDD scores

The baseline median CSDD score was 5, with a range of 0 – 16. The histogram below demonstrates the distribution of baseline CSDD scores in the study population. Scores below 6 are, as a rule, associated with absence of significant depressive symptoms. Scores above 10 indicate probable major depression. The histogram below demonstrates that the scores are skewed to the left with very few participants having significant scores on the CSDD.

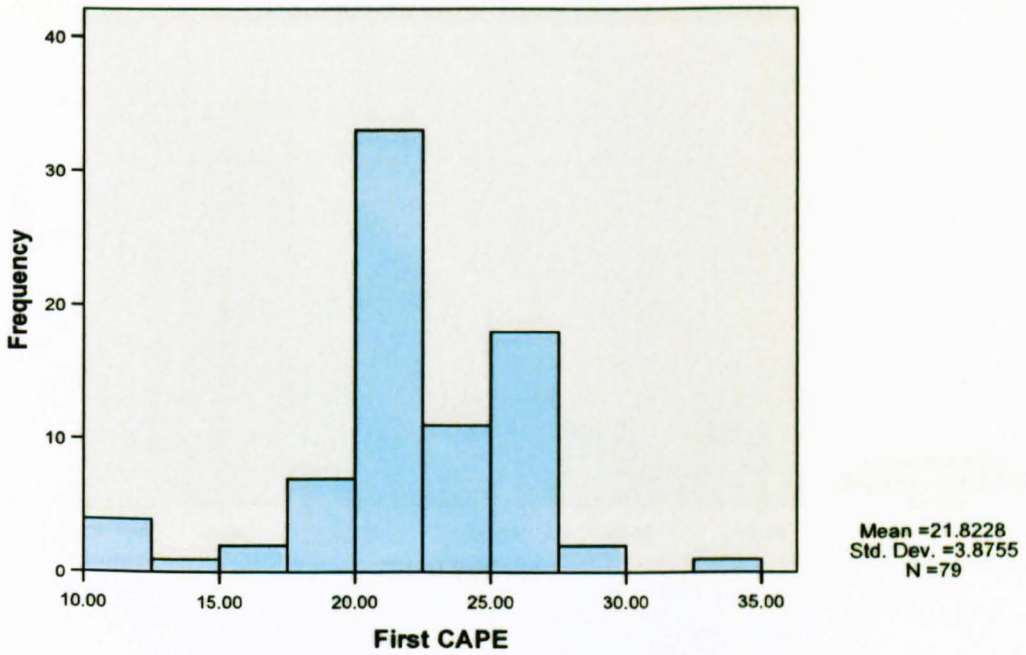
Figure 3.7 Histogram of baseline CSDD scores



### 3.1.5.2 Baseline CAPE-BRS scores

The median baseline CAPE-BRS score was 22 with a range between 11 and 34. The histogram below demonstrates that most of the scores are clustered between 20 and 28, indicating maximum dependency [227].

Figure 3.8 Histogram of baseline CAPE-BRS scores

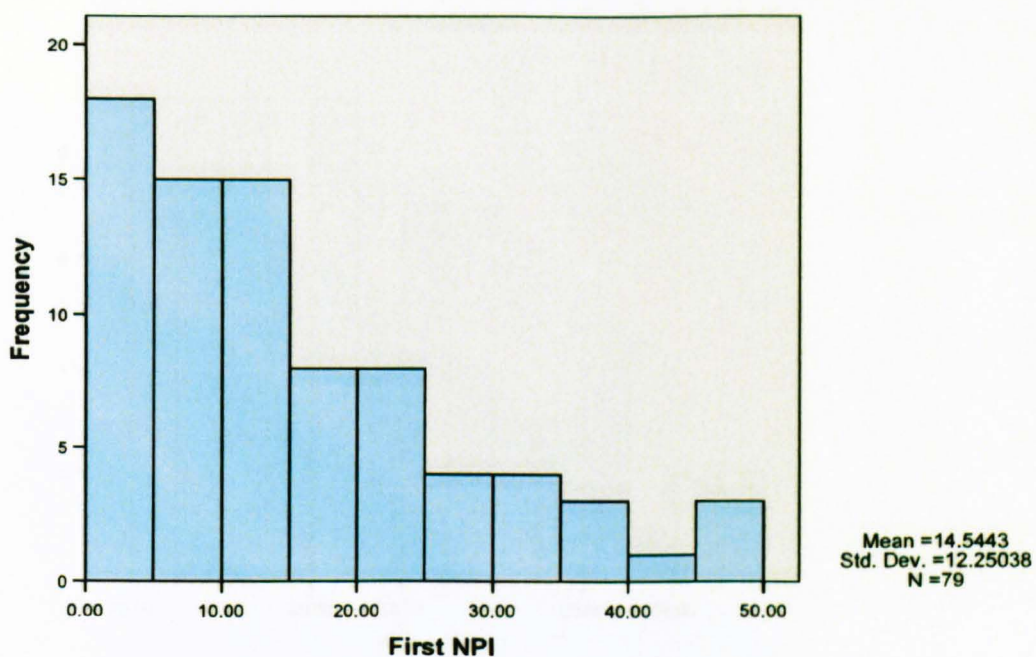




### 3.1.5.3 Baseline NPI scores

The median baseline NPI score was 12, with a range of 0 to 50. The histogram below demonstrates that the scores are skewed to the left.

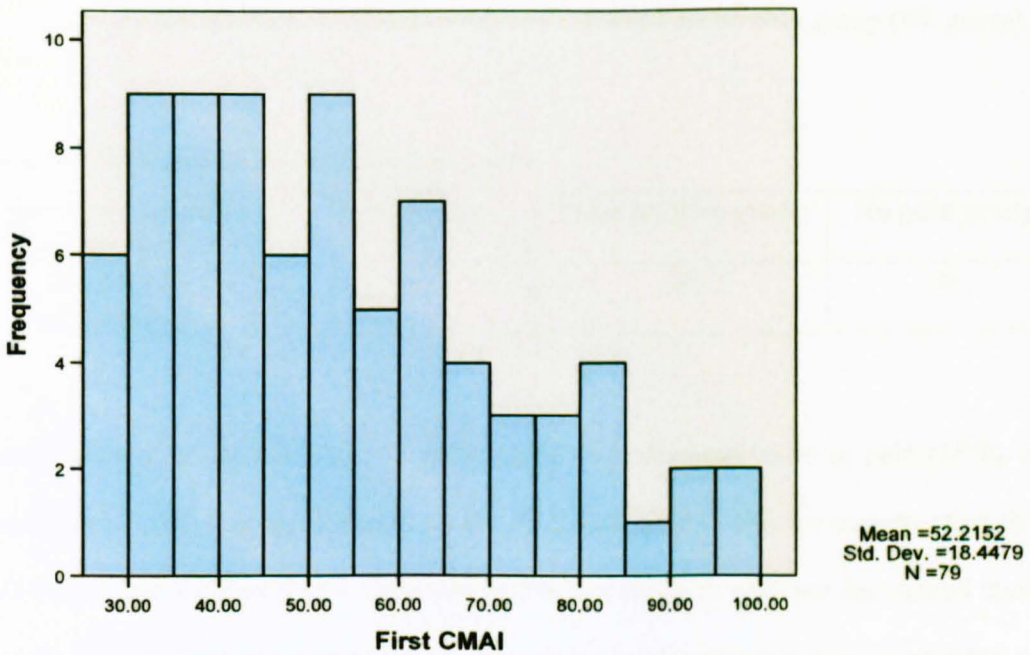
Figure 3.9 Histogram of baseline NPI scores



### 3.1.5.4 Baseline CMAI scores

The median baseline CMAI score was 50, with a range of 29 to 96 (with 29 being the minimum score of the scale).

Figure 3.10 Histogram of baseline CMAI scores



### 3.1.6 Results from baseline assessment

The results from the baseline assessment test the hypothesis that pain is common and under-recognised in this population. Once the three observations forming the baseline assessment were completed, a decision was made as to whether the behaviour observed was caused by pain. The participants who were not felt to be in pain but had scored greater than two on the PAINAD scale at any of the three observations, formed the false positive group (FP group). The other participants who were not felt to be in pain and had not scored greater than two on the PAINAD scale formed the no pain group (NP group).

*Table 3.6 Results from the baseline assessment*

<b>Result from baseline assessment</b>	<b>Pain group</b>	<b>False positive group</b>	<b>No pain group</b>
<b>Number of participants</b>	13	26	40

From the baseline assessments, 13 participants were assessed to be in pain (16%), 26 participants had scored significantly on the PAINAD scale (33%) for reasons other than pain and 40 participants (51%) were assessed as not being in pain nor had scored above two on the PAINAD scale. There was one participant who was felt to be in pain but did not score greater than two at any assessment. They were included in the pain group but could also be considered as the only false negative.

Figure 3.11 Pie chart of outcomes of baseline observation

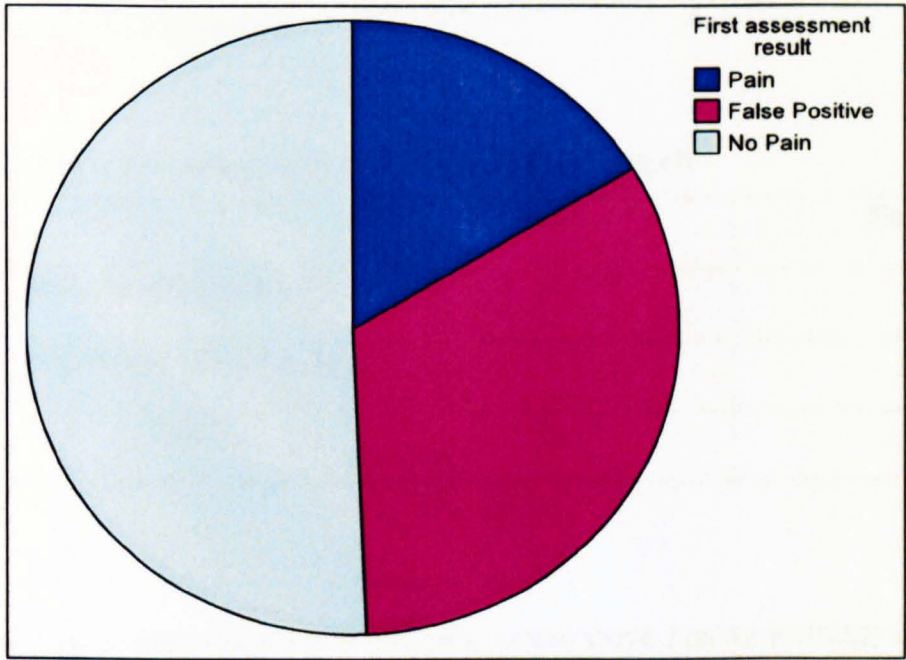
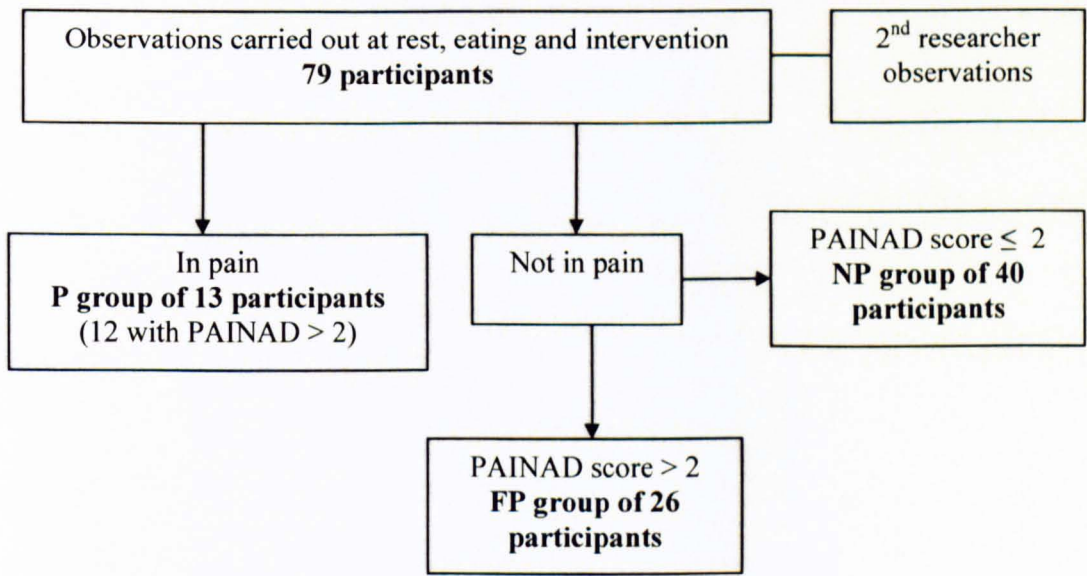


Figure 3.12 Flow chart of outcomes following baseline assessment



The sensitivity and specificity of PAINAD can also be calculated from the results from the baseline assessment.

*Table 3.7 Assessing sensitivity and specificity of PAINAD*

	<b>Pain</b>	<b>No Pain</b>
<b>Positive (PAINAD &gt; 2)</b>	12	26
<b>Negative (PAINAD ≤ 2)</b>	1	40
<b>Total</b>	13	66

12 participants, out of the 13 with pain, scored above 2 on the PAINAD scale. This gives PAINAD a sensitivity of 92%. 40 participants, out of the 66 without pain, scored 2 or below on the PAINAD scale. This gives PAINAD a specificity of 61%.

### 3.2 Results from all three groups

The factors associated with the groups formed following the baseline assessment were analysed to fulfil several study objectives. These were to assess the nature of distress that may produce a false positive result on a pain scale and to examine the use of analgesia in those identified as experiencing pain. Analysis of the factors associated with the pain group could potentially identify subgroups where pain was more common. Owing to some of the expected counts being less than five, the association between the groups and gender, dementia diagnosis, place of residence and analgesia prescribed were analysed using Fishers exact test. Fishers exact test has been extended so that it can be used for  $m$  by  $n$  tables, as it has been in this research.

#### 3.2.1 Background information

##### 3.2.1.1 Participants' gender

*Table 3.8 Association of participants' gender and results from baseline assessment*

<b>First assessment</b>	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Female</b>	8 (14%)	19 (33%)	30 (53%)	57
<b>Male</b>	5 (23%)	7 (32%)	10 (45%)	22
<b>Totals</b>	13	26	40	79

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	0.90	0.703
<b>Fisher's exact test</b>	1.010	0.655

There were no statistically significant differences seen in gender between the groups

### 3.2.1.2 Participants' dementia diagnosis

*Table 3.9 Association of participants' dementia diagnoses and results from baseline assessment*

<b>Dementia diagnosis</b>	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Alzheimer's</b>	6 (14%)	14 (33%)	22 (52%)	42
<b>Lewy Body</b>	1	1	1	3
<b>Vascular</b>	6 (26%)	9 (39%)	8 (35%)	23
<b>Mixed</b>	0	2 (22%)	7 (78%)	9
<b>Downs</b>	0	0	1	1
<b>Not known</b>	0	0	1	1
<b>Total</b>	13	26	40	79

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	8.606	0.610
<b>Fisher's exact test</b>	9.264	0.487

Although there appears to be a greater proportion of those with vascular dementia in the pain group, these differences are not statistically significant.

### 3.2.1.3 Participants' place of residence

*Table 3.10 Association of participants' place of residence and results from baseline assessment*

<b>Place of residence</b>	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Tynemouth Court</b>	3	6	7	16
<b>Willow Court</b>	3	8	7	18
<b>Cleveland Park</b>	3	7	16	26
<b>Appleby Care Home</b>	4	5	10	19
<b>Totals</b>	13	26	40	79

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	3.308	0.785
<b>Fisher's exact test</b>	3.498	0.769

There were no statistically significant differences seen in place of residence between the groups



### 3.2.1.4 Analgesia prescribed for participants

*Table 3.11 Association of participants' analgesia and results from baseline assessment*

<b>Analgesia</b>	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Regular</b>	6	3	2	11
<b>As required</b>	2	11	13	26
<b>No analgesia</b>	5	12	25	42
<b>Total</b>	13	26	40	79

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	15.43	0.003
<b>Fisher's exact test</b>	12.214	0.011

Owing to some of the counts being less than five, the differences between analgesia prescribed and the groups (from the first assessment) have been analysed using Fishers exact test. These differences are significant to  $p = 0.011$ , with almost half of those found to be in pain prescribed regular analgesics compared with 5% of those not in pain. As the numbers within each group are small, it is difficult to carry out further statistical analyses on this data.

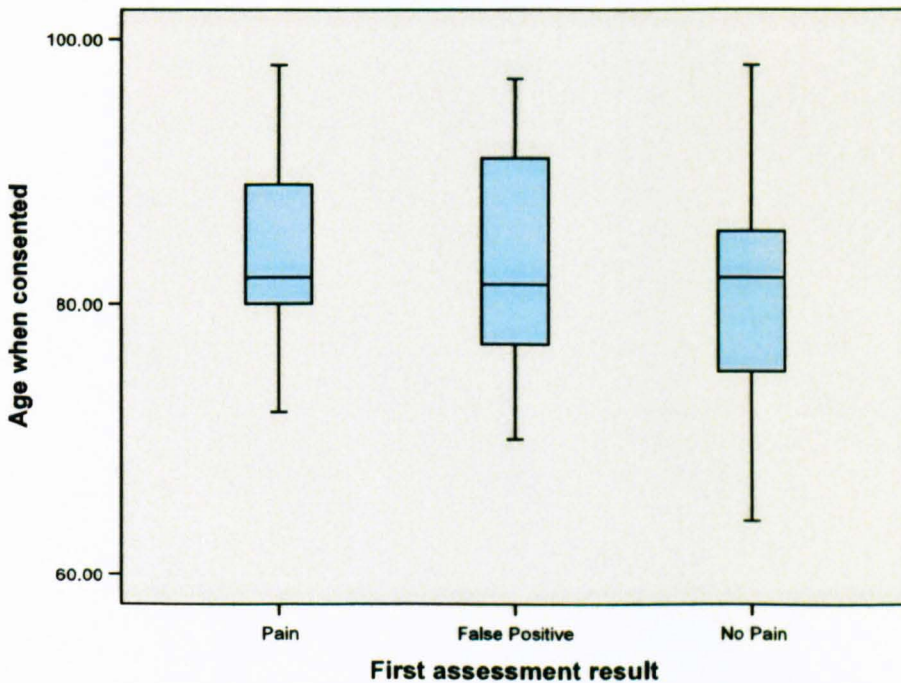
### 3.2.1.5 Participants' age

The mean and standard deviation of the age of each of the groups has been represented in the table below and as a box and whisker plot

Table 3.12 Age of participants of groups following baseline assessment

Age in years	Mean	Standard deviation	Median	Range
P Group	83.2	7.373	82	72 - 98
FP Group	83.7	8.385	81.5	70 - 97
NP Group	80.4	8.047	82	64 - 98

Figure 3.13 Box and whisker plot of participants' age of groups following baseline assessment



The group means for age were further analysed using one-way analysis of variance (ANOVA).

*Table 3.13 Analysis of group means for age*

	<b>Sum of squares</b>	<b>df</b>	<b>Mean square</b>	<b>F</b>	<b>Significance</b>
<b>Between groups</b>	202.598	2	101.299	1.560	0.217
<b>Within groups</b>	4934.946	76	64.934		
<b>Total</b>	5137.544	78			

There are therefore no significant differences between the group means for age.

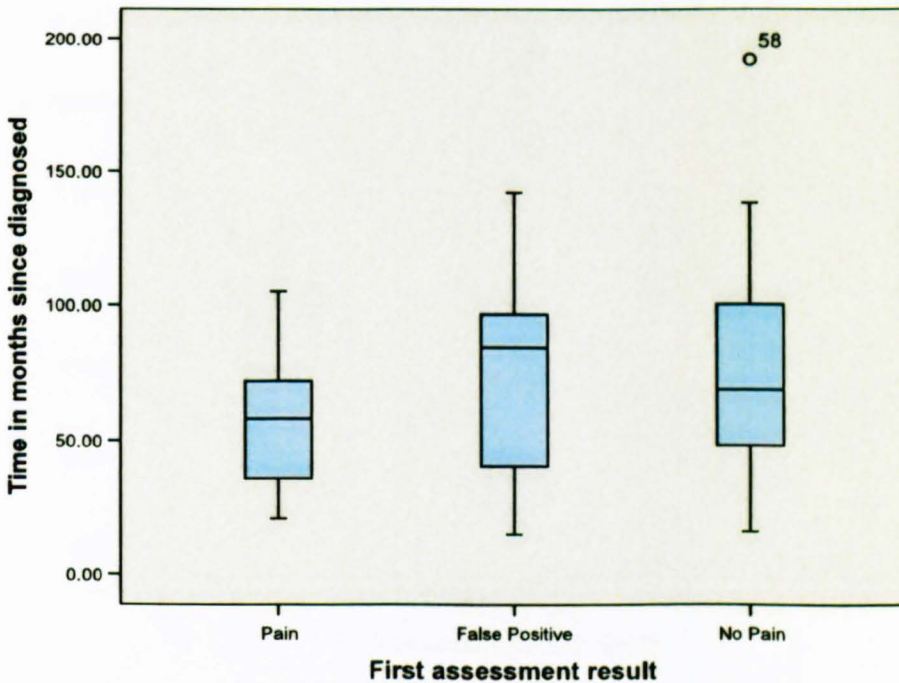
### 3.2.1.6 Time since diagnosis

The mean and standard deviation of the time since diagnosis for each of the groups has been represented in the table below and as a box and whisker plot.

Table 3.14 Time since diagnosis of participants of groups following baseline assessment

Time since diagnosis (in months)	Mean	Standard deviation	Median	Range
P Group	57.8	26.621	58	21 - 105
FP Group	71.3	36.492	84	15 - 142
NP Group	75.6	36.640	68	16 - 192

Figure 3.14 Box and whisker plot of participants' time since diagnosis of groups following baseline assessment



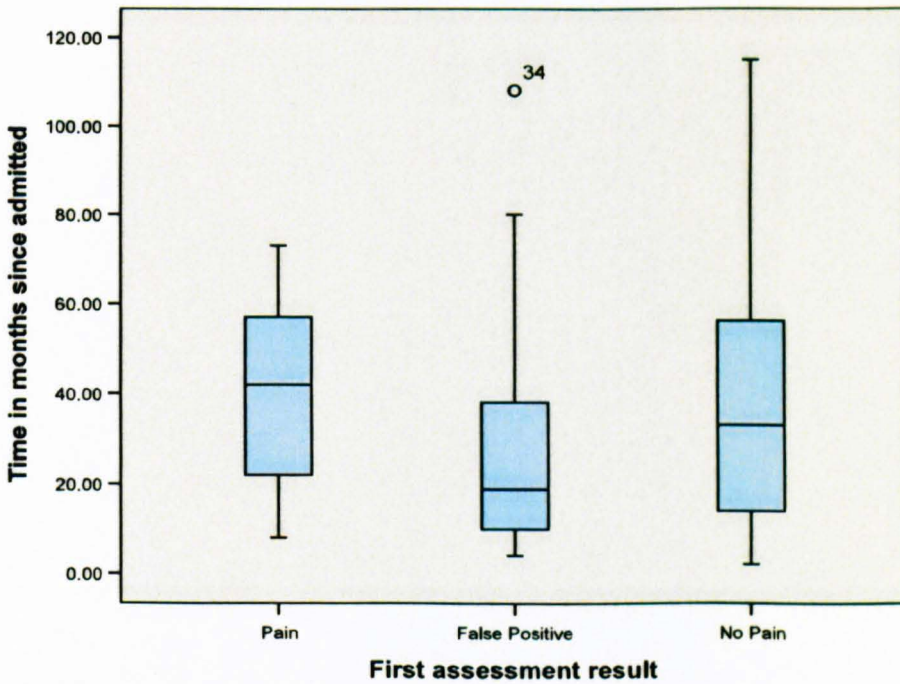
### 3.2.1.7 Time since admission

The mean and standard deviation of the time since admission for each of the groups has been represented in the table below and as a box and whisker plot.

Table 3.15 Time since admission of participants of groups following baseline assessment

Time since admission (in months)	Mean	Standard deviation	Median	Range
P Group	40.5	22.070	42	8 - 73
FP Group	30.6	28.093	19	4 - 108
NP Group	37.5	27.120	33	2 - 115

Figure 3.15 Box and whisker plot of participants' time since admission of groups following baseline assessment



As the time since admitted and time since diagnosed are non-parametric distributions the group means for time since diagnosed and admitted were analysed using the Kruskal-Wallis test.

*Table 3.16 Analysis of group means for time since diagnosis and admission*

	<b>Chi-squared (H) statistic</b>	<b>df</b>	<b>Asymmetrical significance</b>
<b>Time in months since diagnosed</b>	2.718	2	0.257
<b>Time in months since admitted</b>	2.277	2	0.320

Although the time since diagnosis was less for the P group, this difference was not statistically significant. In addition the mean time since admission was much less in the FP group, but this again did not reach statistical significance.



### 3.2.2 Background neuropsychiatric scales

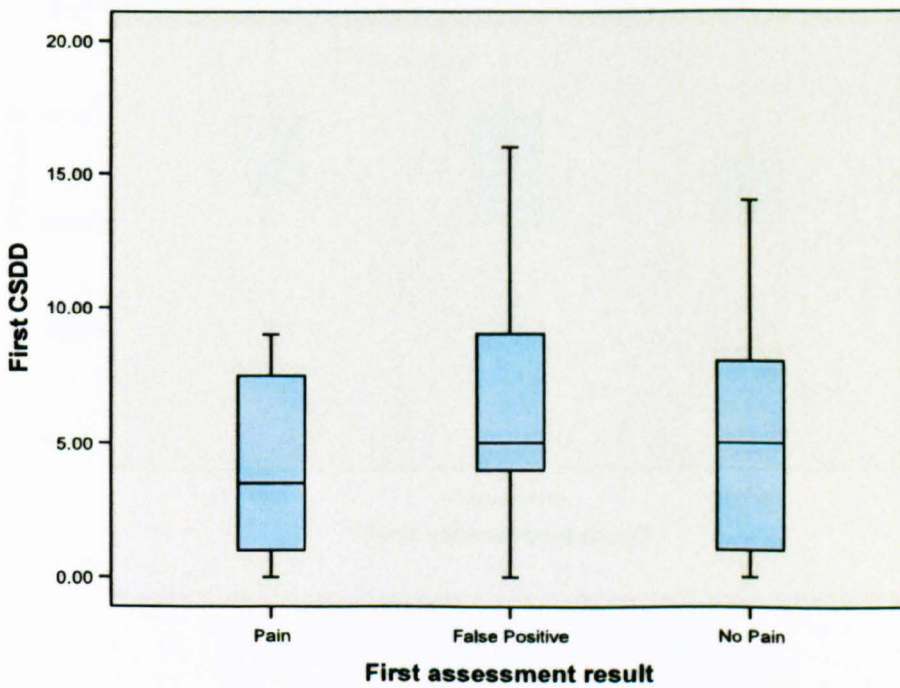
The mean and standard deviation of the background neuropsychological tests for each of the groups has been represented in the table below and as a box and whisker plot.

#### 3.2.2.1 Baseline CSDD

Table 3.17 Baseline CSDD of the groups

Baseline CSDD	Mean	Standard deviation	Median	Range
P Group	4.038	3.315	3.5	0 – 9
FP Group	6.154	4.442	5	0 – 16
NP Group	5.024	4.003	5	0 - 14

Figure 3.16 Box and whisker plot of baseline CSDD of the groups

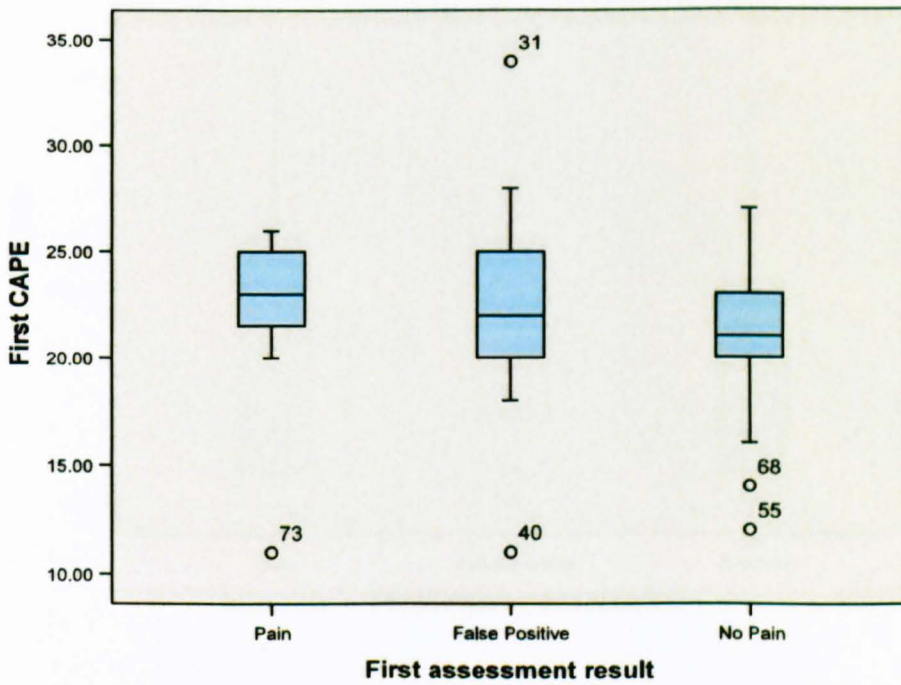


### 3.2.2.2 Baseline CAPE

Table 3.18 Baseline CAPE-BRS of the groups

Baseline CAPE-BRS	Mean	Standard deviation	Median	Range
P Group	22.333	4.075	23	11 - 26
FP Group	22.500	4.320	22	11 - 34
NP Group	21.317	3.517	21	12 - 27

Figure 3.17 Box and whisker plot of baseline CAPE-BRS of the groups



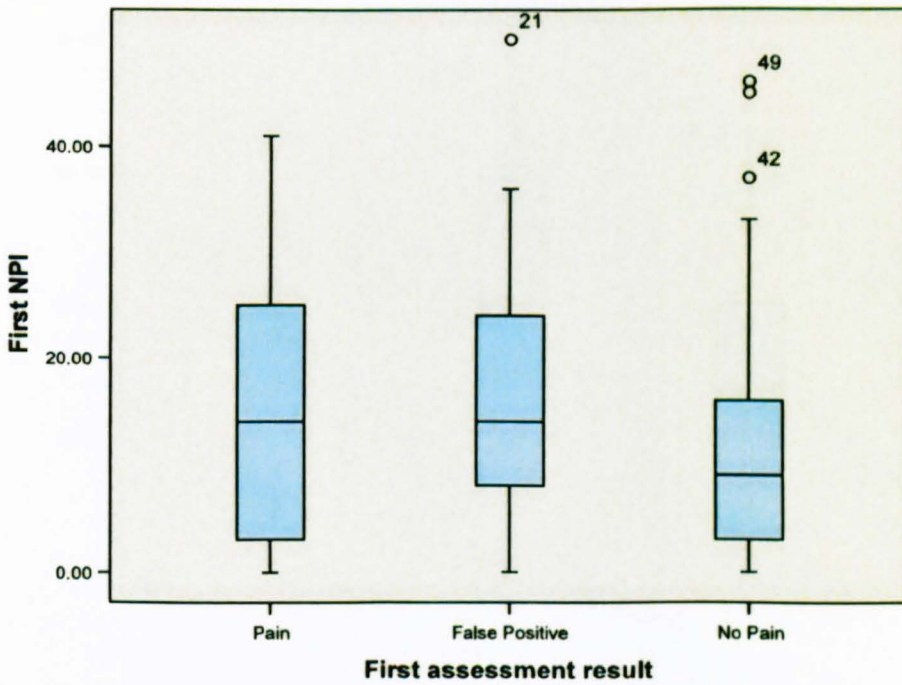


### 3.2.2.3 Baseline NPI

Table 3.19 Baseline NPI of the groups

Baseline NPI	Mean	Standard deviation	Median	Range
P Group	15.417	14.318	14	0 - 41
FP Group	17.308	11.623	14	0 - 50
NP Group	12.073	11.930	9	0 - 46

Figure 3.18 Box and whisker plot of baseline NPI of the groups

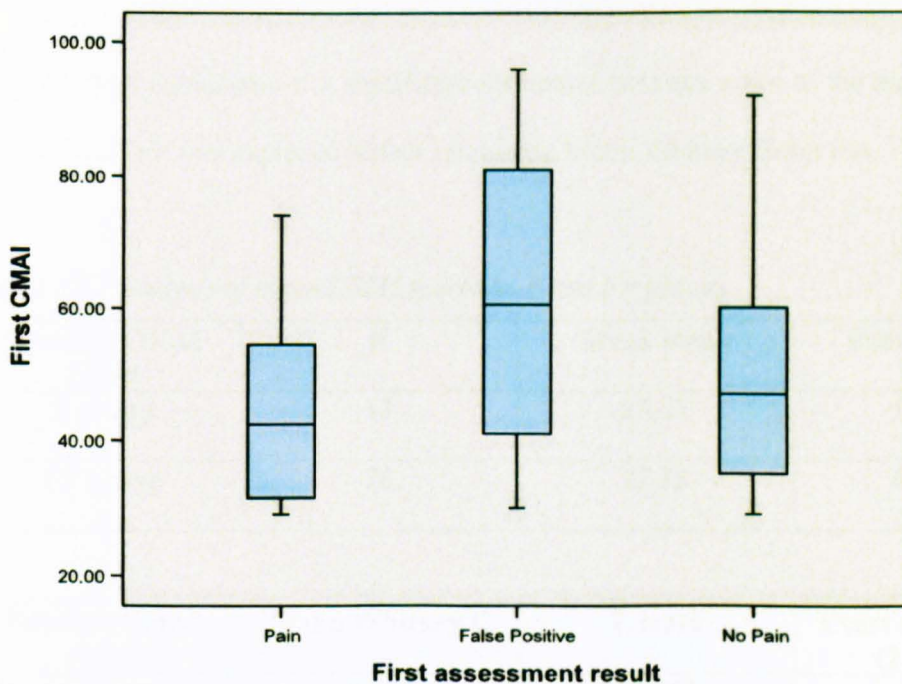


### 3.2.2.4 Baseline CMAI

Table 3.20 Baseline CMAI of the groups

Baseline CMAI	Mean	Standard deviation	Median	Range
P Group	44.25	14.882	42.5	29 – 74
FP Group	60.346	20.731	60.5	30 – 96
NP Group	49.122	16.427	47.0	29 - 92

Figure 3.19 Box and whisker plot of baseline CMAI of the groups



As the background neuropsychiatric scales are non-parametric distributions (non normal) the group means were analysed using the Kruskal-Wallis test.

*Table 3.21 Analysis of group background neuropsychiatric tests*

	<b>Chi-squared (H) statistic</b>	<b>df</b>	<b>Asymp. significance</b>
<b>Baseline CSDD</b>	1.983	2	0.371
<b>Baseline CAPE</b>	1.805	2	0.405
<b>Baseline NPI</b>	4.586	2	0.101
<b>Baseline CMAI</b>	7.790	2	0.020

This analysis demonstrated a significant difference between some of the mean scores of the CMAI. This was explored further by using a Mann-Whitney Exact test.

*Table 3.22 Analysis of mean CMAI scores in P and FP groups*

<b>Baseline CMAI result</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>P group</b>	13	13.77	179.00
<b>FP group</b>	26	23.12	601.00

<b>Baseline CMAI result</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>P and FP groups</b>	88.00	-2.415	0.015

*Table 3.23 Analysis of mean CMAI scores in P and NP groups*

<b>Baseline CMAI result</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>P group</b>	13	23.04	299.50
<b>NP group</b>	40	28.29	1131.50

<b>Baseline CMAI result</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>P and NP groups</b>	208.5	-1.066	0.293

*Table 3.24 Analysis of mean CMAI scores in FP and NP groups*

<b>Baseline CMAI result</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>FP group</b>	26	39.79	1034.50
<b>NP group</b>	40	29.41	1176.50

<b>Baseline CMAI result</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>FP and NP group</b>	356.500	-2.147	0.031

There are significant differences between the mean CMAI scores in the P and FP groups and the NP and FP groups, with mean CMAI scores in the FP group significantly higher than those in the other groups.

### 3.2.3 Comparison of the PAINAD scores for the three groups

This comparison was carried out to test the hypothesis that the pain assessment tool can reliably be used to identify pain.

*Table 3.25 Initial PAINAD scores in P group*

	<b>Mean</b>	<b>Standard deviation</b>	<b>Median</b>	<b>Range</b>
<b>Rest</b>	1.25	2.301	0.5	0 - 8
<b>Eating</b>	0.67	1.073	0	0 - 3
<b>Intervention</b>	5	2.629	4	1 - 8

*Table 3.26 Initial PAINAD scores in FP group*

	<b>Mean</b>	<b>Standard deviation</b>	<b>Median</b>	<b>Range</b>
<b>Rest</b>	1.269	1.68	0	0 - 6
<b>Eating</b>	1.7	1.43	1.5	0 - 5
<b>Intervention</b>	3.192	1.939	3	0 - 7

*Table 3.27 Initial PAINAD scores in NP group*

	<b>Mean</b>	<b>Standard deviation</b>	<b>Median</b>	<b>Range</b>
<b>Rest</b>	0.325	0.526	0	0 - 2
<b>Eating</b>	0.375	0.629	0	0 - 2
<b>Intervention</b>	0.725	0.784	1	0 - 2

The differences between the mean scores for each group were further analysed using the Kruskal-Wallis Test.

*Table 3.28 Analysis of mean initial PAINAD scores of each group*

<b>PAINAD assessment</b>	<b>Groups</b>	<b>N</b>	<b>Mean rank</b>
<b>Initial Rest</b>	P	13	43.15
	FP	26	45.65
	NP	40	35.30
<b>Initial Eating</b>	P	13	36.88
	FP	26	54.56
	NP	40	31.55
<b>Initial intervention</b>	P	13	63.62
	FP	26	52.33
	NP	40	24.31

	<b>First rest PAINAD</b>	<b>First eat PAINAD</b>	<b>First Intervention PAINAD</b>
<b>Chi-squared</b>	4.675	19.298	41.538
<b>df</b>	2	2	2
<b>Asymp. significance</b>	0.97	< 0.001	< 0.001

There is therefore a statistically significant difference between the initial PAINAD scores during the eating and intervention observations and the three groups. This was analysed further using the Mann-Whitney exact test.

### 3.2.3.1 First Eat PAINAD analysis

*Table 3.29 Analysis of first eat PAINAD scores of P and FP groups*

<b>First Eat PAINAD</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>P group</b>	13	14.27	185.5
<b>FP group</b>	26	22.87	594.5

<b>First Eat PAINAD</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>P and FP groups</b>	94.5	-2.298	0.025

*Table 3.30 Analysis of first eat PAINAD scores of P and NP groups*

<b>First Eat PAINAD</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>P group</b>	13	29.62	385.0
<b>NP group</b>	40	26.15	1046.0

<b>First Eat PAINAD</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>P and NP groups</b>	226.0	-0.854	0.377

*Table 3.31 Analysis of first eat PAINAD scores of NP and FP groups*

<b>First Eat PAINAD</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>FP group</b>	26	45.19	1175.0
<b>NP group</b>	40	25.90	1036.0

<b>First Eat PAINAD</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>FP and NP groups</b>	216.0	-4.335	< 0.001

The mean FP group PAINAD eating score was greater than those obtained by the P and NP groups (table 3.26, page 152). As statistically significant differences have been demonstrated between the FP group score and those obtained by the P and NP groups, the FP group score for eating is significantly greater than the P and NP scores for this observation.



### 3.2.3.2 First Intervention PAINAD analysis

*Table 3.32 Analysis of first intervention PAINAD scores of P and FP groups*

<b>First Intervention PAINAD</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>P group</b>	13	24.73	321.5
<b>FP group</b>	26	17.63	458.5

<b>First Intervention PAINAD</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>P and FP groups</b>	107.5	-1.869	0.066

*Table 3.33 Analysis of first intervention PAINAD scores of P and NP groups*

<b>First Intervention PAINAD</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>P group</b>	13	45.88	596.50
<b>NP group</b>	40	20.86	834.5

<b>First Intervention PAINAD</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>P and NP groups</b>	14.5	-5.260	< 0.001

*Table 3.34 Analysis of first intervention PAINAD scores of NP and FP groups*

<b>First Intervention PAINAD</b>	<b>N</b>	<b>Mean Rank</b>	<b>Sum of ranks</b>
<b>FP group</b>	26	48.19	1253.0
<b>NP group</b>	40	23.95	958.0

<b>First Intervention PAINAD</b>	<b>Mann Whitney U</b>	<b>Z score</b>	<b>Exact significance (2 tailed)</b>
<b>FP and NP groups</b>	138.0	-5.164	< 0.001

The mean NP group PAINAD intervention score was less than those obtained by the P and FP groups (table 3.27, p153). As statistically significant differences have been demonstrated between the NP group score and those obtained by the P and FP groups, the NP group score for intervention is significantly less than the P and FP scores for this observation. Although the mean P group PAINAD score for intervention was greater than that obtained by the FP group, this was not statistically significant ( $p = 0.066$ )

### **3.2.4 Summary of results from all three groups**

The three groups have been looked at as a whole to examine factors associated with having pain or producing a false positive result on the PAINAD scale. There was no significant association with the participants' sex, dementia diagnosis or place of residence with the results from the first assessment. There was however a significant association between analgesia prescribed prior to the assessment and the first assessment result ( $p = 0.011$ ).

There was no significant association demonstrated between age, time since admission and time since diagnosis. There was no significant association between the background neuropsychiatric tests and the first assessment result, apart from the CMAI scores. This association was evaluated further, demonstrating that the CMAI scores for the false positive group were significantly different compared to those obtained by participants in the P and NP groups.

There were significant differences between the initial PAINAD scores for the eating and intervention assessments ( $p < 0.001$ ). It was demonstrated that the mean PAINAD score for the eating observation was significantly greater for the FP group compared with the other groups. In addition it was demonstrated that the mean PAINAD scores on intervention for the NP group were significantly less than those obtained for the FP and P groups.

### 3.3 Results from pain and false positive groups

#### 3.3.1 Pain group

The following analyses were carried out to test the hypotheses that the PAINAD and DisDAT tools are sensitive to change and that pain can be managed using both simple pharmacological and non-pharmacological techniques.

*Table 3.35 Underlying causes of pain and treatment changes*

<b>Number</b>	<b>Cause of pain</b>	<b>Treatment used</b>
TC 2	Contractures	Regular Paracetamol
TC 16	Dental Caries	Tooth extraction/ filling, as required Paracetamol
TC 23	Arm tension owing to anxiety	Massage
WC 9	Pain on sitting on hard surfaces	Pressure area care on washing
WC 20	Rheumatoid arthritis of knee	Topical NSAIDs
WC 22	Contractures	Regular Paracetamol
CP 17	Cellulitis and DVT of leg	Antibiotics/Cocodamol/Tinzaparin
CP 19	Arthritis/ previous hip fracture	Slow Release Tramadol
CP 25	Arthritis/ immobility	Regular Paracetamol
AP 6	Arthritis	Change in time of analgesia
AP 9	Hand contracture	Procyclidine (started by participant's GP)
AP 17	Pain on sitting on hard surfaces	Not left sitting on hard surfaces
AP 25	Pain on cleaning nails	Acute incident therefore staff alerted to it

The medication charts were reviewed prior to the 1 month assessment and all the suggested drug changes had been made. The medication charts were reviewed prior to the 3 month assessment; most of the medication was still prescribed at the time of the 3 month assessment. There were two exceptions, the CP17 drug changes (as the cellulitis had resolved) and CP19 drug changes (problems with supply of slow release tramadol, therefore temporarily given short acting tramadol). The changes in patient management were documented in care plans and were acted upon during the assessments at 1 and 3 months. The massage therapy (for WC 23) had just commenced at the time of the 1 month assessment and was continuing at the 3 month assessment.

### 3.3.1.1 Background neuropsychiatric scales

The data from these scales was non parametric, hence the pairs of observations were analysed using the Wilcoxon signed-rank test.

*Table 3.36 Analysis of the differences between baseline and 1 month background neuropsychiatric scales of the P group*

	<b>Second CAPE – First CAPE</b>	<b>Second CMAI – First CMAI</b>	<b>Second CSDD – First CSDD</b>	<b>Second NPI – First NPI</b>
<b>Z score</b>	-1.811 <sup>a</sup>	-1.337 <sup>b</sup>	-0.211 <sup>b</sup>	-1.334 <sup>b</sup>
<b>Asymp. Significance</b>	0.070	0.181	0.833	0.182

a) Based on negative ranks

b) Based on positive ranks

There were no significant differences observed between the initial background neuropsychiatric scales and those carried out after making a treatment change for pain.

### 3.3.1.2 Assessment results ~ initial and 1 month scores

The change in assessment scores following change in treatment was also analysed using the Wilcoxon signed ranks test owing to the data being non-parametric.

*Table 3.37 Analysis of the differences between initial and 1 month assessment scores of the P group*

	<b>First rest DisDAT-1 month rest DisDAT</b>	<b>First rest PAINAD -1 month rest PAINAD</b>	<b>First eat DisDAT-1 month eat DisDAT</b>	<b>First eat PAINAD -1 month eat PAINAD</b>	<b>First intervention DisDAT-1 month intervention DisDAT</b>	<b>First intervention PAINAD -1 month intervention PAINAD</b>
<b>Z score</b>	-0.367 <sup>a</sup>	-0.530 <sup>b</sup>	-1.897 <sup>a</sup>	-0.990 <sup>a</sup>	-2.670 <sup>b</sup>	-2.653 <sup>b</sup>
<b>Asymp Significance</b>	0.714	0.596	0.058	0.322	0.008	0.008

a) Based on positive ranks

b) Based on negative ranks

For both DisDAT and PAINAD scales post treatment scores were significantly lower than pre treatment scores (both  $p = 0.008$ ). These were both based on the negative ranks, therefore the scores post treatment were significantly lower than those recorded pre treatment.

### 3.3.1.3 Assessment results ~ 1 month and 3 month scores

The change in assessment scores at 3 months was also analysed using the Wilcoxon signed ranks test owing to being non-parametric.

*Table 3.38 Analysis of the differences between 1 month and 3 month assessment scores of the P group*

	<b>3 month rest DisDAT- 1 month rest DisDAT</b>	<b>3 month rest PAINAD -1 month rest PAINAD</b>	<b>3 month eat DisDAT- 1 month eat DisDAT</b>	<b>3 month eat PAINAD -1 month eat PAINAD</b>	<b>3 month intervention DisDAT-1 month intervention DisDAT</b>	<b>3 month intervention PAINAD -1 month intervention PAINAD</b>
<b>Z score</b>	0.000 <sup>a</sup>	-0.216 <sup>b</sup>	-1.703 <sup>b</sup>	-1.222 <sup>b</sup>	-1.357 <sup>c</sup>	-1.035 <sup>c</sup>
<b>Asymp Significance</b>	1.000	0.829	0.088	0.222	0.175	0.301

- a) The sum of negative ranks equals the sum of positive ranks
- b) Based on positive ranks
- c) Based on negative ranks

There were no significant differences demonstrated between the results obtained at 1 month and those obtained at 3 months in the pain group.



### **3.3.1.4 Clinical Vignettes**

There were several different underlying causes of the pain identified during the study. Some were due to acute events such as cellulitis, others were due to more chronic problems such as arthritis. The vignettes below describe how some of the painful conditions were managed, the potential benefits of using pain/distress tools and some of the challenges of managing pain in such patients.

#### **3.3.1.4.1 Vignettes 1a and b**

These vignettes have been chosen to illustrate how tools can help guide management as well as the need for regular assessments.

An 81 year old lady, who had been diagnosed with vascular dementia seven years previously, had been resident in the home for six years. She had been bed bound for some time and a previous stroke had left her with contractions of the left arm and leg. She became distressed whilst being dressed, grimacing, tensing up and groaning. She scored four during intervention on the PAINAD tool and the distress behaviours identified on the DisDAT increased during times of intervention. It seemed to be the movement of her contracted limbs that caused pain and this hadn't improved greatly despite regular baclofen. She was therefore started on regular paracetamol in addition to the baclofen for musculoskeletal pain. The change in medication was reviewed as outlined in the method section and discussed with the nursing home staff. They were unclear whether the additional paracetamol had made much difference. The assessment tools were therefore repeated which demonstrated a clear improvement on both tools. This was still

observable three months after starting the medication. In this way the tools had helped to demonstrate a reduction in pain behaviours and hence an improvement associated with commencing regular paracetamol.

A 79 year old lady with dementia with Lewy bodies was observed to groan, frown and become tense during intervention. She had contractures of her arms and it was clear when her arms were moved that the behaviours were more obvious. She was started on regular paracetamol, and review after one month showed a reduction in the scores of both tools. Further observation at three months demonstrated that this improvement had not been maintained, as there was a recurrence of the behaviours seen on the initial observation. This highlights the progressive nature of conditions and the need for regular review.

#### **3.3.1.4.2 Vignette 2a and b**

These vignettes have been selected to exemplify the potential difficulties in assessing what the cause of distress is, and that several causes of distress may be present during one observation. The first vignette also illustrates the issues surrounding the time frame that behaviours are present for.

An 83 year old gentleman with vascular dementia (WC 9) was observed to become particularly agitated during bath times, shouting, swearing and hitting out at staff. He scored 7 on the PAINAD tool at bath times and many of the distress behaviours from the DisDAT tool were also observed. The staff felt he had always been very difficult to manage and just hated having anyone “interfering with him”. There are clearly many

potential causes of distress that can occur when bathing elderly people with dementia [233] and attempting to ascertain which may be the cause of such behaviours observed can take several observations. It became clear that this participant's distress was much more apparent when he was sitting on the bath seat (e.g. constantly shouted "get me off!") and was resolved to a certain extent when he was standing up. At other times he would be distressed when sitting on the toilet, but would sit without any distress on a relieving cushion whilst in the residents' lounge. There were no obvious signs of pressure damage to his buttocks but he had clearly lost weight, potentially making sitting on hard surfaces uncomfortable. It was therefore decided after discussion with the staff to try showering him instead and use towels to cushion the shower chair. The staff noticed that this did help, which was also demonstrated to a certain extent when repeating the assessment tools. On the occasion of repeating the observation he was more settled whilst being showered, however became agitated when the staff struggled to put his shirt on which was too small for him. As the length of time which a particular behaviour is present for can be reflected when using the PACA score with the DisDAT, the DisDAT score was reduced. The PAINAD score remained almost the same (8 out of 10), reflecting the episode of agitation whilst being dressed.

An 80 year old gentleman with vascular dementia had a history of severe degenerative arthritis of the left hip as well as having broken his right hip and pelvis caused by a fall a year previously. Despite having a terrible short term memory, the memory of the fall and the pain suffered from the fall were still very fresh in his mind. Each time he was helped out of bed he would shout that he was going to fall and it would hurt, despite repeated

reassurances from the staff that they had him well supported. On observation it was difficult to decide whether he was in pain or was becoming distressed on account of a fear of falling and fear of being in pain. It required a further observation to recognise that both were probably the case. His analgesic medication was adjusted to control his pain more effectively. The scores were reduced after changing his medication, but some of the fears regarding falling remained since his difficulties with short term recall meant that any reassurances given were quickly forgotten.

These cases demonstrate the difficulties in understanding exactly the causes of the observed behaviours. In both cases the participants were in pain, but other factors also caused distress, such as fear of falling or agitation caused by dressing. In identifying and managing the painful aspects of washing or dressing, the scores on the tools were reduced and hence the overall distress was reduced. There may, however, be additional factors that are more difficult to manage, such as deeply held fears. The first case also demonstrates that without a time frame built into a scale, results can be skewed by behaviours that weren't present for all of the observation period.

#### **3.3.1.4.3 Vignette 3**

This vignette demonstrates some of the challenges in finding a suitable treatment strategy that is acceptable to the participant. One 97 year old participant with Alzheimer's disease became distressed on being helped out of bed. She had a history of arthritis of her hip (seen on X-ray) and was chair-bound during the day. It was difficult for her to localise her pain: sometimes she would describe hip pain, but occasionally other joints seemed to

be painful. She was started on regular paracetamol. However, she would frequently refuse to take this, as she did with many of her other medications. She was, therefore, started on Calpol (paracetamol in liquid form) with some success; however she would still intermittently spit it out or refuse to take it. The staff felt she was better when taking the analgesia regularly but at times just couldn't be persuaded that it would be of benefit to her to take her medication. More local therapies were discussed, but owing to the difficulty in knowing exactly where the pain was located these were not tried. Various non-pharmacological therapies, such as massage, had been tried previously without success. In addition, this participant frequently complained that she would rather be left alone; therefore the non-pharmacological strategies which had previously failed were not retried. The PAINAD and DisDAT scores remained relatively unchanged throughout, mainly as there was no guarantee that the day of repeating the scores was a day that she had been complying with her medication. The extent to which the behaviours observed were caused by pain was very difficult to assess, particularly as a proper trial of medication was impossible. A plan was made, therefore, to continue to observe closely for potential pain and distress and use paracetamol as appropriate.

### 3.3.2 False positive group

The following analyses were carried out to assess the nature of distress that may produce a false positive result on a pain assessment tool.

*Table 3.39 Underlying causes for the false positive scores*

<b>Number</b>	<b>Cause for PAINAD score &gt;2</b>
<b>TC 19</b>	<b>Upset by other residents</b>
<b>TC 21</b>	<b>Not understanding leading to embarrassment</b>
<b>TC 22</b>	<b>Not understanding leading to aggression</b>
<b>TC 24</b>	<b>Mood related and not understanding</b>
<b>TC 27</b>	<b>Not understanding leading to anxiety</b>
<b>TC 29</b>	<b>Upset by other residents and not understanding</b>
<b>WC 3</b>	<b>Not understanding and emotionally labile</b>
<b>WC 4</b>	<b>Irritation at being fed and possible hallucinations</b>
<b>WC 6</b>	<b>Frustration at inability to communicate, dislike of shaver and loud noises</b>
<b>WC 10</b>	<b>Not liking food, irritated by others</b>
<b>WC 13</b>	<b>Anxiety caused by not understanding</b>
<b>WC 14</b>	<b>Hearing loss hence not understanding</b>
<b>WC 21</b>	<b>Boredom</b>
<b>WC 25</b>	<b>Transient low mood (resolved without intervention)</b>

<b>Number</b>	<b>Cause for PAINAD score &gt;2</b>
<b>CP 22</b>	<b>Mood related (grumpy some mornings!)</b>
<b>CP27</b>	<b>Upset by other resident</b>
<b>CP 30</b>	<b>Not understanding leading to frustration</b>
<b>CP 33</b>	<b>Visual loss causing difficulty in managing food</b>
<b>CP40</b>	<b>Not understanding leading to anger and frustration</b>
<b>CP41</b>	<b>Not understanding leading to anxiety and fear</b>
<b>CP42</b>	<b>Feeling cold</b>
<b>AP2</b>	<b>Not understanding leading to frustration</b>
<b>AP14</b>	<b>Not understanding leading to anxiety and fear</b>
<b>AP20</b>	<b>Possible sadness with anxiety at general situation</b>
<b>AP23</b>	<b>Sadness at situation/emotional lability</b>
<b>AP29</b>	<b>Generally feeling unwell, nauseated</b>

### 3.3.2.1 Background neuropsychiatric scales

The data from these scales was non-parametric, hence the pairs of observations were analysed using the Wilcoxon signed-rank test.

*Table 3.40 Analysis of the differences between baseline and 1 month background neuropsychiatric scales of the FP group*

	<b>Second CAPE – First CAPE</b>	<b>Second CMAI – First CMAI</b>	<b>Second CSDD – First CSDD</b>	<b>Second NPI – First NPI</b>
<b>Z score</b>	-0.474 <sup>a</sup>	-2.070 <sup>a</sup>	-0.731 <sup>b</sup>	-1.476 <sup>a</sup>
<b>Asymp. Significance</b>	0.635	0.038	0.465	0.140

a) Based on positive ranks

b) Based on negative ranks

There was a significant difference ( $p = 0.038$ ) between the second and first CMAI scores in the FP group. As this calculation was based on the positive ranks, there was a significant decrease in CMAI score at the time of the second assessment.



### 3.3.2.2 Assessment results ~ initial and 1 month scores

The observations were simply repeated at 1 month for the FP group. The data was also analysed using the Wilcoxon signed ranks test as it was non-parametric.

*Table 3.41 Analysis of the differences between initial and 1 month assessment scores of the FP group*

	<b>First rest DisDAT-1 month rest DisDAT</b>	<b>First rest PAINAD -1 month rest PAINAD</b>	<b>First eat DisDAT-1 month eat DisDAT</b>	<b>First eat PAINAD -1 month eat PAINAD</b>	<b>First intervention DisDAT-1 month intervention DisDAT</b>	<b>First intervention PAINAD -1 month intervention PAINAD</b>
<b>Z score</b>	-2.448 <sup>a</sup>	-2.121 <sup>a</sup>	-1.292 <sup>a</sup>	-0.450 <sup>a</sup>	-1.427 <sup>a</sup>	-2.026 <sup>a</sup>
<b>Asymp Significance</b>	0.014	0.034	0.196	0.653	0.154	0.043

There was a significant difference seen between the initial and 1 month scores for DisDAT at rest and PAINAD at rest ( $p = 0.014$  and  $p = 0.034$ ), as well as the initial and 1 month scores for PAINAD on intervention. These were all based on negative ranks; hence there was a significant reduction in scores at 1 month on both scales at rest and the PAINAD score on intervention.

### 3.3.2.3 Assessment results ~ 1 month and 3 month scores

The change in assessment scores at 3 months was also analysed using the Wilcoxon signed ranks test owing to being non-parametric.

*Table 3.42 Analysis of the differences between 1 month and 3 month assessment scores of the FP group*

	<b>3 month rest DisDAT- 1 month rest DisDAT</b>	<b>3 month rest PAINAD -1 month rest PAINAD</b>	<b>3 month eat DisDAT- 1 month eat DisDAT</b>	<b>3 month eat PAINAD -1 month eat PAINAD</b>	<b>3 month intervention DisDAT-1 month intervention DisDAT</b>	<b>3 month intervention PAINAD -1 month intervention PAINAD</b>
<b>Z score</b>	-2.060 <sup>a</sup>	-0.541 <sup>a</sup>	-0.827 <sup>a</sup>	-0.137 <sup>a</sup>	-1.115 <sup>a</sup>	-1.011 <sup>a</sup>
<b>Asymp Significance</b>	0.039	0.589	0.408	0.891	0.265	0.312

a) Based on negative ranks

There was a significant difference seen between the 1 month and 3 month scores using the DisDAT at rest. As this was based on the negative ranks, the 3 month rest DisDAT was significantly greater than the 1 month rest DisDAT. There were no other statistically significant differences demonstrated.

#### **3.3.2.4 Clinical Vignettes**

There was a proportion of participants in the study who scored above two on the PAINAD tool, owing to reasons other than being in pain. The causes of the behaviour seen were discussed with the nursing staff and fell into broad sub groups. Many of the participants in the study frequently did not seem to understand what was happening or what was being asked of them. This often led to the participant appearing anxious or frightened by what was going on around them or, for some participants, angry and frustrated that they were not able to do simple tasks and were having to be helped. Other participants seemed to be upset by other residents within the home and their reactions to these residents were the behaviours described on the PAINAD tool. Some participants simply appeared to have good or bad days, with changeable moods owing to unidentified causes, whilst others reacted to their environment, displaying behaviours presumed to be caused by boredom or generalised sadness, possibly reflecting a degree of insight. At times it was difficult to be certain as to the cause of the behaviour seen and occasionally the behaviour resolved without specific treatment. The vignettes below describe some of the causes for a false positive result on the PAINAD tool in more detail and the challenges faced in determining the cause for the behaviours identified during the observations.

#### **3.3.2.4.1 Vignettes 4a and b**

An 81 year old gentleman with Alzheimer's disease was noted to use negative speech, frown and become tense whilst having a bath, needing to be reassured. He therefore scored four on the PAINAD tool and displayed several of the distress behaviours identified by the DisDAT. During bath time he became quite puzzled and unsure as to what was happening and what certain things were for. He was quite easily reassured and smiled and laughed whilst being bathed. It therefore seemed that the times of not understanding caused him to frown, become tense, use negative speech and he needed to be reassured to ease his anxiety over what was happening. Similar behaviour was also seen when he was observed having a meal. Again, once he understood why he had to sit at a table with others for his meal, the observed behaviour resolved and therefore it could be concluded that it was not due to pain. By evaluating what had caused the behaviours to start and to stop, it was clear that the cause for the observed behaviour was not pain.

An 82 year old lady with vascular dementia appeared to react to not understanding by becoming angry and frustrated. When being helped out of bed and dressed, she became very angry, demanding that people get away from her and then proclaiming "Oh why can't I do it, what is wrong with me?". She tried to hit or kick anyone who came near her and did not respond to any reassurance or explanation. Once she was dressed she was quite calm and happy to be taken into the dining room for breakfast. She therefore scored seven on the PAINAD tool and displayed many of the distress behaviours documented for her on the DisDAT. When she was reviewed the following month she was much calmer and allowed the carers to wash and dress her without becoming as angry. This was

possibly because the home allocated certain carers to her so that she would recognise what they were trying to do and, therefore, be less aggressive towards them. Her scores were correspondingly lower at the second observation.

These two vignettes help to illustrate different reactions that may be seen in those with dementia who are unable to understand what is happening around them. There were several other participants in this group who had similar reactions when unable to comprehend situations, some being more amenable to reassurance than others. This demonstrates the importance of the psychosocial environment for people with dementia [234].

#### **3.3.2.4.2 Vignette 5a and b**

A 79 year old lady with Alzheimer's disease was observed pacing the corridors of the nursing home, frowning and muttering to herself. She would happily talk to the staff and denied any pain, but refused to sit in the main lounge with the other residents. During observation her PAINAD score was 3 and the pacing, frowning and muttering were all behaviours of distress that had been documented on her DisDAT assessment. She was then shown a quieter lounge without anyone sitting in it and when sitting in the quieter lounge, the behaviours resolved. It seemed, therefore, that the behaviours observed were due to her dislike of being in a room with large numbers of other residents and her need for a quiet space.

A 93 year old lady with Alzheimer's was observed to frown, mutter and become restless whilst sitting at rest, scoring 3 on the PAINAD tool. This seemed mainly on account of another resident sitting next to her asking her questions, which she did not understand and which caused her to become irritated. Owing to mobility problems, she was unable to move to another seat. The behaviours were resolved by a staff member suggesting that the resident questioning her should leave her alone and move to a different area of the lounge.

Both these vignettes describe participants displaying behaviour caused by the general nursing home environment. The behaviours observed during these vignettes were alleviated by allowing space for quietness within the nursing home and by vigilance on the part of nursing staff. Several review articles have suggested that changes to the environment, such as allowing for quieter areas, may help to reduce agitated behaviour [70, 235, 236].

#### **3.3.2.4.3 Vignette 6**

A 77 year old lady with long-standing Alzheimer's disease scored four on the PAINAD tool whilst being fed and five when being dressed in the morning. She was immobile and unable to communicate verbally. When being fed, she would grimace and become tense when the spoon was put in front of her mouth, but once she opened her mouth and ate the food, the behaviour resolved. It was concluded that the behaviour was probably due to not understanding what was happening whilst being fed. This participant also displayed similar behaviour when being dressed, which was much more obvious when she initially

was helped out of bed. The observed behaviour again might be caused by her misunderstanding the situation, leading to anxiety, but also it was felt that some of it might be due to pain. The participant had a history of osteoarthritis and was noted by staff members to be very stiff when first helped up. With this in mind a trial of regular paracetamol was proposed: sadly she died before this could be commenced. In the last few days of life the grimacing behaviour was noted to be occurring more frequently and she was prescribed oral morphine, by the emergency GP, to be given as needed. The staff felt that when the analgesia was given, there was no obvious difference to the grimacing behaviour, so it is possible that the cause of the behaviour was not pain. This vignette, similar to the participants in vignettes 2a and b, demonstrates that the cause of the behaviours observed is sometimes difficult to ascertain. In addition, it may be necessary to consider a trial of analgesia if the cause could potentially be pain.

#### **3.3.2.4.4 Vignette 7**

A 98 year old lady with dementia was observed to call out and moan loudly at rest and during intervention, giving her a PAINAD score of three. The staff had noted a change in this lady over several few days, becoming more withdrawn, refusing to eat or take any medication. At rest she would call out that she was being starved, yet refuse to eat and would groan and frown when being undressed. The GP had reviewed her and felt that this was due to her dementia progressing and she was nearing the end of life, with which family and staff agreed with. She denied any pain and was able to move without causing distress. This included her left hip, on which she had had surgery following a fracture. One hypothesis was that she was depressed; however, the withdrawal behaviour

gradually improved over a matter of days. When the scales were repeated there was a marked reduction in both scores which was sustained at 3 months. It was not clear to anyone involved in her care what the cause of the deterioration was, but it resolved without any specific intervention.

#### **3.3.2.4.5 Vignette 8**

A 94 year old lady with vascular dementia would become very distressed on being helped to get dressed, giving her a PAINAD score of three. She would scream loudly if left unattended and became frustrated by the nursing staff trying to help her to get dressed. The behaviours did not seem to be movement related and once she was dressed she became quite calm. It was therefore decided that the behaviours observed were not pain related and were potentially caused by wanting attention and by feelings of frustration. Shortly after the observation had taken place, she had a fall and fractured her left hip. She was admitted to hospital, had a dynamic hip screw inserted and discharged back to the nursing home. When the repeat observation was carried at one month she displayed similar behaviours as during the initial observation but also seemed to become distressed on movement, particularly of her left leg. This was highlighted to the staff who asked for the GP to review her. She was subsequently started on regular paracetamol as it was felt that she had movement related pain of her left hip. Although this participant was originally assigned to the false positive group on the basis of the behaviours observed, she subsequently was observed to be in pain on repeat observation. This vignette highlights the importance of repeat evaluation of behaviours observed as the underlying cause may change over time.



These clinical vignettes for those with a false positive result from the PAINAD tool highlight important issues surrounding the management of pain in those with severe dementia. In the first instance, using a PAINAD tool in isolation will incorrectly identify observed behaviour as pain, whereas there may be a range of different causes for the behaviour, as highlighted by the above clinical vignettes. The underlying cause may actually change over time as highlighted by vignette 8. It is possible that using a PAINAD tool simply identifies some of the behavioural and psychological symptoms of dementia (BPSD) which then have to be evaluated to identify the underlying cause. It is well established in the literature surrounding the management of “challenging behaviour” in dementia that identifying the antecedents to the behaviour is important in assessing the cause [67, 236] and the same is true when assessing behaviour that might be caused by pain. Utilising this approach, the underlying cause of many of the observed behaviours could be established. Some of the behaviours observed responded to reassurance, with others simply resolving over time.

### 3.3.3 Comparison of P and FP group scores

Further analysis was also carried out to investigate whether the change in scores at the 1 month assessment for both PAINAD and DisDAT were different in the P and FP groups.

As the data was non-parametric, this was carried out using the Mann-Whitney test.

*Table 3.43 Analysis of the change in scores at 1 month of P and FP groups*

	<b>Mann Whitney U</b>	<b>Z Score</b>	<b>Exact Significance (2 tailed)</b>
<b>Rest DisDAT</b> 1 month - initial	61.5	-1.920	0.062
<b>Rest PAINAD</b> 1 month - initial	75.5	-1.349	0.215
<b>Eat DisDAT</b> 1 month - initial	61.0	-2.256	0.039
<b>Eat PAINAD</b> 1 month - initial	84.5	-1.124	0.281
<b>Intervention DisDAT</b> 1 month - initial	75.0	-1.501	0.145
<b>Intervention PAINAD</b> 1 month - initial	106.0	-0.191	0.869

This demonstrates that the changes seen between the scores obtained initially and at one month for the two groups were not significantly different apart from the DisDAT scores obtained whilst eating. The median change in the P group was greater than the median change in the FP group; hence for this observation the change in DisDAT score was significantly greater in the P group. As this result just reaches significance and was the only significant result seen in this analysis, it is possible that this is a type one error. Repeat analysis would be necessary to investigate this further.

### **3.3.4 Summary of results from pain and false positive groups**

The table on p160 documents the underlying causes for the pain observed, with both acute and chronic pain causes observed. A variety of strategies were used to manage the pain, employing both pharmacological and non pharmacological techniques. Despite the study participants all having started treatment for their pain, a significant change in the background neuropsychological tests was not seen. There was, however, a significant change seen on repeating the assessment tools. A statistically significant change ( $p = 0.008$ ) was seen in both the DisDAT and PAINAD scores for the intervention observation following treatment for pain. This confirms the hypothesis that the tools are sensitive to change. There was no significant change seen when the assessments were repeated at the 3 month stage. The issues surrounding assessment and management of pain are explored in more detail using the case vignettes.

The underlying causes for the behaviour seen in the false positive group are documented in the table on p170 and 171. The background neuropsychological tests were repeated one month after the initial tests were carried out. Despite specific interventions having not been suggested for the participants of this group, a statistically significant reduction in the CMAI score was demonstrated. In addition, a statistically significant reduction was also demonstrated in both the DisDAT and PAINAD scores at rest and the PAINAD score on intervention when the assessments were repeated at one month. The assessments were also repeated 3 months after the baseline assessments were carried out, with a statistically significant increase in the DisDAT score demonstrated at rest. The issues

surrounding assessing and managing the behaviour seen in this group of participants are also explored further using the clinical vignettes.

Finally, analysis was also carried out to examine whether the magnitude of the change in scores differed between the pain and false positive groups. No statistically significant differences were demonstrated apart from the DisDAT scores obtained whilst eating. In this observation, the change in DisDAT score was significantly greater in the P group than the FP group.

### **3.4 Analysis of behaviours documented and observed**

These analyses were carried out to provide further information on the breadth of behaviours that may be associated with distress in those with severe dementia and how various factors may influence the number of behaviours seen. In addition, these analyses provide information on the behaviours observed by those experiencing pain and how this may differ from the behaviours observed by those in the false positive group. This explores further the reliability of both PAINAD and DisDAT in identifying pain.

#### **3.4.1 DisDAT**

The DisDAT (Disability Distress Assessment Tool) is designed to identify distress cues in people with severely limited communication. It is completed by carers documenting behaviours of distress and behaviours seen when that person is content. The tool was originally created for use with people with limited communication owing to learning difficulties. By completing the tool for the 79 participants in this study, data has therefore been collected regarding behaviours of distress seen in people with severe dementia.

##### **3.4.1.1 Behaviours of distress identified using DisDAT**

From 79 study participants, 129 different behaviours of distress were documented, with 72 behaviours documented for only one person. Several distress behaviours were commonly documented; the 20 commonest distress behaviours are documented in the table overleaf.

<b>Documented behaviour of distress</b>	<b>Number of participants</b>
Frown	52
Louder words or shouts	35
Restless	30
Tearful or cries	30
Grimaces	28
Becomes tense	25
Moans or groans	24
Eats less or won't eat	22
Frightened expression	20
Screams	19
Stares	18
Flushed skin	18
Hits out	15
Faster breathing	13
Tries to bite staff	13
Clammy skin	12
Rigid posture	12
Swears	11
Won't allow anyone to come close	11
Startled expression	10

*Table 3.44 20 commonest distress behaviours documented using DisDAT*

### 3.4.1.2 Unique behaviours

There were 72 behaviours of distress that were documented in only one participant. These have been divided up into the headings in which they were described when completing the DisDAT. The unique distress behaviours under each heading for all participants are shown in the table below.

*Table 3.45 Number of unique distress behaviours per DisDAT heading*

<b>Behaviour</b>	<b>Number of unique behaviours</b>
Facial signs	7
Eye appearance	4
Skin appearance	1
Vocal sounds	11
Speech	22
Habits and mannerisms	13
Body posture	11
Body observations	3

The unique behaviours of distress are outlined in more detail in the table overleaf.

<b>Facial signs</b>	<b>Eye appearance</b>	<b>Skin appearance</b>	<b>Vocal sounds</b>	<b>Speech</b>	<b>Habits and mannerisms</b>	<b>Body posture</b>	<b>Body observations</b>
Opens mouth wide	Dilated pupils	Face goes red	Sighs	Copies the voices of others	Rubs forehead	Increased rocking	Faster pulse
Tongue protrudes further out	Rolls eyes		Cries without tears	Tells you off	Blows out lips	Sits forward	Deep breathing
Thin lips	Good eye contact		Constant moan	Complains	Puts self on the floor	Marches around	Can't concentrate on eating
Looks sullen	Narrows eyes		Loud trilling noise	Calls out for Grandparents	Waves fist	Draws legs up	
Looks vacant			Sharp tone	Says "I'm going to die"	Breathes through teeth	Jerky posture	
Glares			Grunts	Threatens to kill you	Pulls pads out	Leans back when walking	
Looks through you			Shrieks	Loud and fast foreign words	Refuses to do things	Folds arms	
			Louder moan/groan	Says "don't"	Rolls up trouser legs	Runs away	
			Tuts	Gives out instructions	Wringing hands	Pulls head back when drinking	
			Harsh tone	Calls out "the bairns"	Head butts	Shuffles in chair	
			Goes quiet		Shakes any hands gripped	Crawls around floor	

*Table 3.46 Unique distress behaviours documented for study participants*

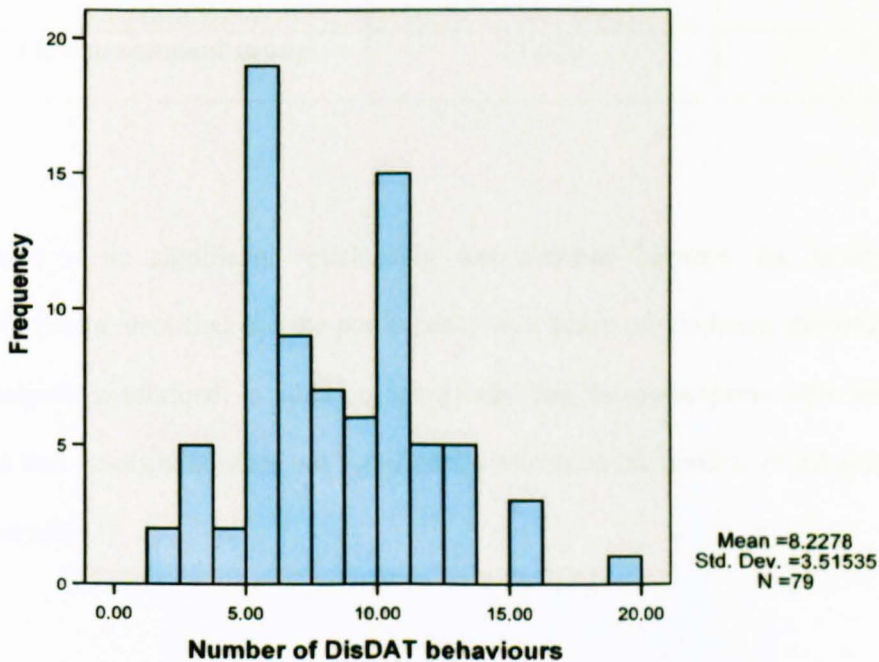


Other habits and mannerisms were slamming doors and leaving the meal table. There were 12 other speech behaviours including asking for help, saying “Oh God” and asking for tablets.

### 3.4.1.3 Numbers of behaviours of distress

For the 79 study participants, the mean number of behaviours of distress identified was 8.22, with a range of 2 – 19. The histogram below demonstrates the distribution of the number of distress behaviours identified. Analysis using Kolmogorov – Smirnov Test of Normality suggested that this data is not normally distributed.

Figure 3.20 Histogram of distribution of the number of distress behaviours identified



### 3.4.1.3.1 Correlations of number of behaviours of distress with background data

The relationship between the number of behaviours of distress and sex, diagnosis, home, analgesia prescribed and pain, false positive and no pain groupings was analysed. As the data is non-parametric, the Kruskal-Wallis test was used.

*Table 3.47 Analysis of the relationship between categorical background variables and the number of behaviours of distress*

<b>Background variable</b>	<b>Test statistic</b>	<b>Significance (p value)</b>
<b>Sex</b>	8.855	0.840
<b>Home</b>	12.118	0.597
<b>Dementia diagnosis</b>	20.578	0.113
<b>Analgesia prescribed</b>	12.602	0.558
<b>First assessment group</b>	11.670	0.633

There is no significant relationship demonstrated between the number of distress behaviours identified and the participants' sex, place of residence, dementia diagnosis or analgesia prescribed. In addition, the groups that the participants were assigned to after the first assessment, were not significantly related to the number of behaviours of distress identified.

The number of behaviours of distress was correlated with age, time since diagnosis and time since admission to home. As the data is non-parametric Spearman's correlation coefficient was calculated.

*Table 3.48 Analysis of the relationship between continuous background variables and the number of behaviours of distress*

<b>Background variable</b>	<b>Correlation Coefficient (Spearman's)</b>	<b>Significance (2 tailed) (p value)</b>
<b>Age at consent</b>	0.082	0.473
<b>Time since dementia diagnosis</b>	-0.202	0.085
<b>Time since admitted to home</b>	-0.168	0.144

There were no significant correlations between the number of behaviours of distress and age, time since diagnosis and time since admission.

### 3.4.1.3.2 Correlations of number of behaviours of distress with background neuropsychiatric scales

The number of behaviours of distress was correlated with the initial background neuropsychiatric scales. As the data is non-parametric Spearman's correlation coefficient was calculated.

*Table 3.49 Analysis of the relationship between the background neuropsychiatric scales and the number of behaviours of distress*

<b>Neuropsychiatric scale</b>	<b>Correlation Coefficient (Spearman's)</b>	<b>Significance (2 tailed) (p value)</b>
<b>CSDD</b>	0.29	0.01
<b>CAPE-BRS</b>	-0.052	0.650
<b>NPI</b>	0.48	< 0.01
<b>CMAI</b>	0.467	< 0.01

There is a weak correlation between the distress behaviours and initial CSDD scores. The correlation between initial CMAI and NPI scores is moderate.

**3.4.1.4 Number of behaviours of distress observed during observations where pain was present**

The table below denotes the number of distress behaviours, generated using the DisDAT, that were observed during observation where pain was assessed to be present.

*Table 3.50 Number of distress behaviours observed when pain was assessed to be present*

<b>Participant</b>	<b>No of DisDAT distress behaviours seen when in pain</b>
<b>TC 2</b>	<b>2</b>
<b>TC 16</b>	<b>4</b>
<b>TC 23</b>	<b>3</b>
<b>WC 9</b>	<b>8</b>
<b>WC 20</b>	<b>6</b>
<b>WC 22</b>	<b>4</b>
<b>CP 17</b>	<b>5</b>
<b>CP 19</b>	<b>4</b>
<b>CP 25</b>	<b>2</b>
<b>AP 6</b>	<b>1</b>
<b>AP 9</b>	<b>3</b>
<b>AP 17</b>	<b>1</b>
<b>AP 25</b>	<b>2</b>

### 3.4.2 PAINAD

The mean, median standard deviation and range of PAINAD scores has been calculated for P and FP groups, as well as the commonest scoring behaviours. To evaluate the commonest scoring behaviours documented for the pain and false positive groups, the assessments that scored greater than two were collated for each group. There were 15 assessments where PAINAD was > 2 and the participant was felt to be in pain and 34 assessments where PAINAD was > 2 and the participant was not felt to be in pain (false positive group). The chart below shows the PAINAD behaviours for each score.

Figure 3.21 PAINAD tool [3]

	0	1	2
<b>Breathing independent of vocalisation</b>	Normal	Occasional laboured breathing. Short period of hyperventilation	Noisy laboured breathing. Long period of hyperventilation. Cheyne-Stokes respirations
<b>Negative vocalisation</b>	None	Occasional moan or groan Low-level speech with a negative or disapproving quality	Repeated troubled calling out. Loud moaning or groaning. Crying
<b>Facial expression</b>	Smiling or inexpressive	Sad. Frightened. Frown	Facial grimacing
<b>Body language</b>	Relaxed	Tense Distressed pacing. Fidgeting	Rigid. Fists clenched. Knees pulled up Pulling or pushing away. Striking out
<b>Consolability</b>	No need to console	Distracted or reassured by voice or touch	Unable to console, distract or reassure

*Table 3.51 Distribution of initial scores where PAINAD > 2 (Pain group)*

	<b>Breathing</b>	<b>Negative vocalisation</b>	<b>Facial expression</b>	<b>Body language</b>	<b>Consolability</b>
<b>1</b>	3	6	5	4	3
<b>2</b>	0	4	6	4	4
<b>Total</b>	3	10	11	8	7

None of the participants who were felt to be in pain scored 2 for their breathing (i.e. had noisy laboured breathing or Cheyne-Stokes respiration). There was an even spread of the other scores.

*Table 3.52 Distribution of initial scores where PAINAD > 2 (False Positive group)*

	<b>Breathing</b>	<b>Negative vocalisation</b>	<b>Facial expression</b>	<b>Body language</b>	<b>Consolability</b>
<b>1</b>	1	24	21	16	26
<b>2</b>	0	8	6	4	3
<b>Total</b>	1	32	27	20	29

Again none of the participants in the false positive group scored 2 for their breathing. The breathing domain underscored compared with the other domains. The false positive group tended to score lower on each of the other domains as compared to the pain group. This is also reflected in lower mean and median scores in the FP group on intervention. These differences, however, were not found to be significant ( $p = 0.066$ )

In the assessments where the PAINAD score was greater than 2, the distress behaviours from the DisDAT that had been observed during that assessment were also collated. The 10 most frequent behaviours are shown below. The number of times the behaviour was observed is shown in brackets.

*Table 3.53 Distress behaviours observed where PAINAD > 2*

<b>Distress behaviours in False positive group</b>	<b>Distress behaviours in pain group</b>
Frown (21)	Frown (4)
Grimace (9)	Grimace (4)
Screaming (8)	Tense (4)
Louder voice/shouts (7)	Moan/Groan (3)
Restless (6)	Louder voice/shouts (3)
Tense (6)	Muttering (2)
Cries (5)	Hits out (2)
Flushed skin (4)	Faster breathing (2)
Staring (4)	Looks frightened (2)
Looks frightened (4)	Restless (1)

As the number of times a specific behaviour was seen was small, particularly in the pain group, further statistical analysis was not possible.



### **3.4.3 Summary of analysis of behaviours documented and observed**

By completing the DisDAT with the participants' carers, information has been generated regarding distress behaviours seen in those with advanced dementia. From the 129 different behaviours generated from the tool, the most frequent behaviour, frowning, was only documented for 52 participants. Hence even very common behaviours of distress may not be seen universally. From the 72 behaviours that were only documented in one participant, most of these were associated with vocal sounds and speech or habits and mannerisms and body posture.

Further analysis was carried out regarding the factors associated with the number of distress behaviours documented. The Kruskal Wallis test was used to demonstrate that there was no significant association between the number of behaviours of distress and a participant's gender, dementia diagnosis, analgesia prescribed, place of residence or first assessment result. In addition, no significant correlation was demonstrated between the number of behaviours of distress and age, time since diagnosis and time since admission using Spearman's correlation coefficient. A weak correlation was demonstrated between the number of behaviours of distress and CSDD scores and a moderate correlation with CMAI and NPI scores.

By examining the number of DisDAT distress behaviours observed when a participant was in pain, it was possible to demonstrate that on every occasion there was at least one observable behaviour of distress. Therefore, by creating a list of distress behaviours for each participant, distress behaviours caused by pain could be identified.

Analysis of the PAINAD scores (that were > 2) demonstrated that the breathing domain scored infrequently compared to the other domains in both the P and FP groups. The PAINAD scores were more evenly distributed in the P group, with the FP group tending to score lower. By collating the DisDAT behaviours that had scored when the PAINAD score had been > 2, it was possible to compare scoring behaviours for the P and FP groups. This demonstrated that many of the behaviours were the same in both P and FP groups even though the underlying cause for the behaviours was different.

### 3.5 Medication results

#### 3.5.1 Analgesia

The following analyses test the hypotheses that analgesics may be prescribed inadequately for those with dementia and pain can be managed using both simple pharmacological and non-pharmacological techniques.

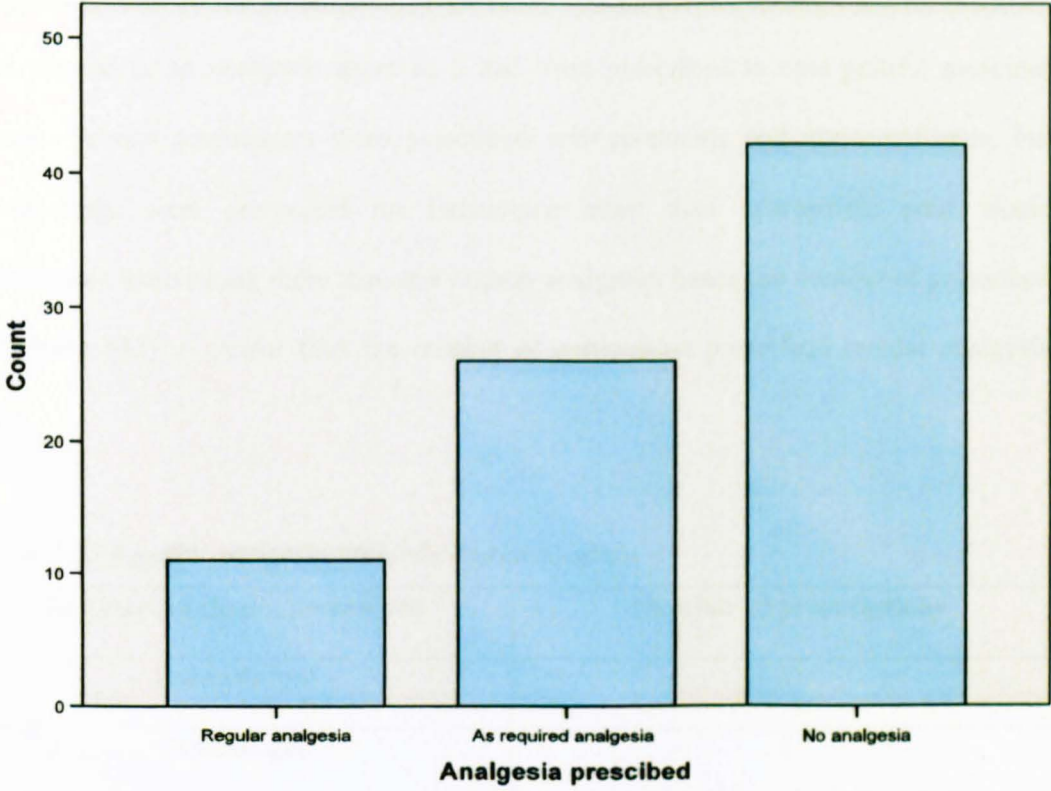
##### 3.5.1.1 Analgesia prescribed prior to study

All those participating in the study had their medications documented on commencement of the study. This was organised into 3 categories; regular analgesia (excluding aspirin), as required analgesia or no analgesia. Regular analgesia included those on both regular and as required analgesia. This has been represented below in tabular and bar chart form.

*Table 3.54 Analgesia prescribed prior to study*

<b>Analgesia prescribed</b>	<b>Regular</b>	<b>As required (PRN)</b>	<b>None</b>
<b>No of participants</b>	11	26	42

Figure 3.22 Histogram of analgesia prescribed prior to study



### 3.5.1.1.1 Regular analgesia

The type of analgesia prescribed was also documented. Paracetamol was prescribed most frequently; none of the participants in the study was prescribed strong opioids. Baclofen was classed as an analgesic agent as it had been prescribed to ease painful muscular spasm. Several participants were prescribed antidepressants and anticonvulsants, but these drugs were prescribed for indications other than neuropathic pain. Some participants were taking more than one regular analgesic, hence the number of prescribed analgesics (13) is greater than the number of participants prescribed regular analgesia (11).

*Table 3.55 Regular analgesia prescribed prior to study*

<b>Regular Analgesia prescribed</b>	<b>Number of prescriptions</b>
<b>Paracetamol</b>	<b>7</b>
<b>NSAID gel</b>	<b>1</b>
<b>Oral NSAID</b>	<b>1</b>
<b>Cocodamol</b>	<b>1</b>
<b>Codeine Phosphate</b>	<b>1</b>
<b>Tramadol</b>	<b>1</b>
<b>Baclofen</b>	<b>1</b>

### 3.5.1.1.2 As required analgesia

The table below illustrates the analgesia prescribed on an as required (PRN) basis. Again by far the most common prescription was for paracetamol.

*Table 3.56 As required analgesia prescribed prior to study*

<b>As required analgesia prescribed</b>	<b>Number of prescriptions</b>
<b>Paracetamol</b>	26
<b>Cocodamol</b>	3
<b>Codeine Phosphate</b>	1

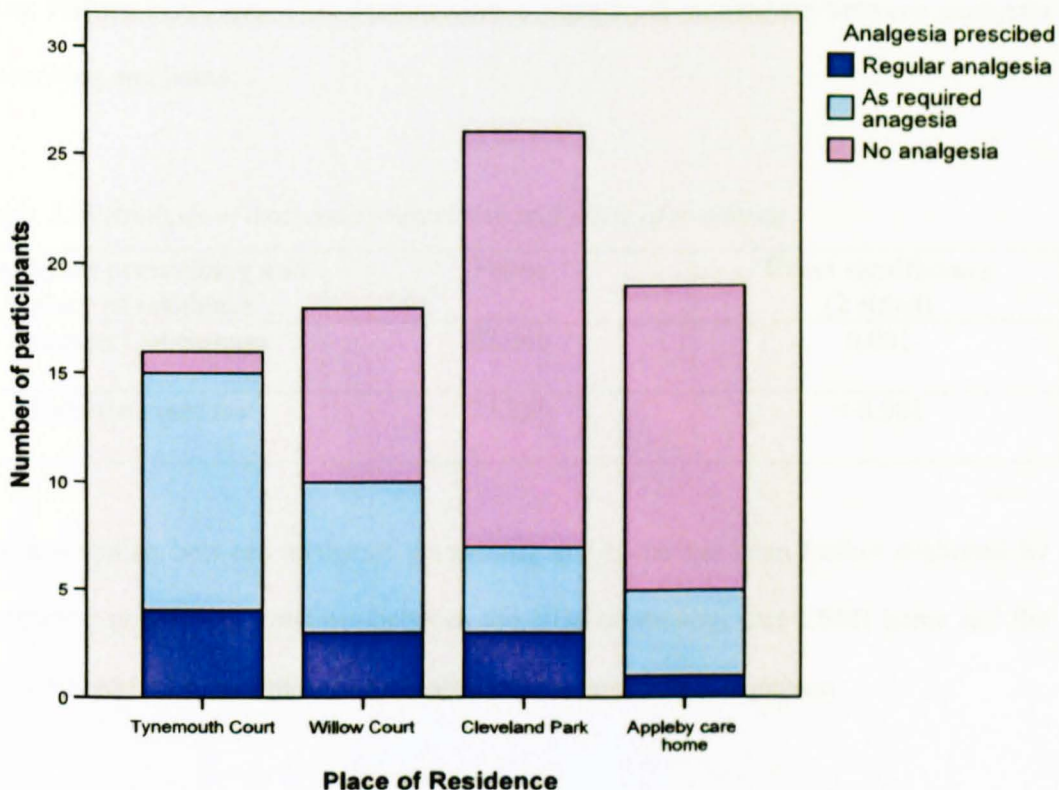
### 3.5.1.1.3 Comparing prescribing practice between homes

The differences in analgesic prescribing between the four homes have been represented in the table and histogram below.

*Table 3.57 Analgesic prescribing in the four homes*

<b>Analgesia Prescribed</b>	<b>Tynemouth Court (TC)</b>	<b>Willow Court (WC)</b>	<b>Cleveland Park (CP)</b>	<b>Appleby (AP)</b>
<b>Regular</b>	4 (25%)	3 (17%)	3 (12%)	1 (5%)
<b>As required (PRN)</b>	11 (69%)	7 (39%)	4 (15%)	4 (21%)
<b>None</b>	1 (6%)	8 (44%)	19 (73%)	14 (74%)
<b>Total</b>	16	18	26	19

Figure 3.23 Histogram of analgesic prescribing in the 4 homes



From displaying the results graphically, it is clear that there are differences in prescribing practices between the homes. Most participants from Tynemouth Court were either on regular analgesia or as required analgesia. Most participants from Cleveland Park and Appleby care homes were not prescribed any analgesia.

The differences of analgesia prescribing between the homes have been evaluated further using Fishers exact test. This demonstrates a significant association between analgesia prescribing and home.

*Table 3.58 Analysis of analgesia prescribing and place of residence*

<b>Analgesia prescribing and place of residence</b>	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	22.640	0.001
<b>Fisher's exact test</b>	23.859	< 0.001

The association between analgesia prescribing and home has been further evaluated by comparing prescribing practices between the NHS continuing care ESMI home and the non-NHS EMI homes. This was again evaluated using Fishers exact test.

*Table 3.59 Comparison of analgesic prescription in NHS and non-NHS homes*

	<b>NHS Home</b>	<b>Non-NHS Homes</b>
<b>Regular analgesia</b>	4	7
<b>As required analgesia</b>	11	15
<b>No analgesia</b>	1	41
<b>Total</b>	16	63

<b>Analgesia prescribing and type of home</b>	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	17.904	< 0.001
<b>Fisher's exact test</b>	19.372	< 0.001



There was therefore a significant difference between analgesic prescribing practices in the NHS home compared to the non-NHS homes. The values are too small in each group for further statistical analysis, however from examining figure 3.23 on p 203 it is possible to see that almost all residents in the NHS home had analgesia prescribed in some form, either as required or regularly. Further data from additional homes would be required to investigate whether these differences are seen more widely and what the implications might be.

The analgesic prescribing practices of the three non-NHS homes were also evaluated using Fishers exact test. This demonstrated that the differences in analgesic prescribing practice were not significant.

*Table 3.60 Analysis of prescribing practice between non-NHS homes*

	<b>Willow Court</b>	<b>Cleveland Park</b>	<b>Appleby Care Home</b>
<b>Regular analgesia</b>	3	3	1
<b>As required analgesia</b>	7	4	4
<b>No analgesia</b>	8	19	14
<b>Total</b>	18	26	19

<b>Analgesia prescribing and non-NHS home</b>	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	5.293	0.265
<b>Fisher's exact test</b>	5.181	0.260

### **3.5.1.2 Summary of analgesia results**

From examining the drug charts prior to the assessments commencing, most participants were not prescribed any analgesics. Of those who were prescribed regular analgesia, most were prescribed paracetamol, with the others prescribed either NSAID or a weak opioid. There were no participants who had been prescribed strong opioids.

Those participants that had been prescribed “as required” analgesia were again mainly prescribed paracetamol. A few participants had been prescribed codeine in combination with paracetamol or codeine alone.

A significant association was demonstrated between analgesia prescription and the home involved in the study. Additional analysis demonstrated a significant difference in prescribing practice between the NHS and non NHS homes. Further statistical analysis of the data was not possible; however, examination of the results graphically demonstrated that the majority of NHS home participants had been prescribed analgesia. No significant differences were demonstrated in prescribing practice in the three non NHS homes. Analysis carried out earlier in this chapter also demonstrated a significant association between analgesia prescribing and the results of the first assessment.

### 3.5.2 Central nervous system drugs

All participants had their medication documented on commencement of the study. Those with primarily central nervous system activity were then grouped into five categories in accordance with their description in the BNF [211]. The groups were antidepressants, anxiolytic/hypnotics, antiepileptics, antipsychotics and dementia drugs. The number of participants prescribed these medications regularly are summarised in the table below.

*Table 3.61 Central nervous system drugs prescribed for study participants*

	<b>Antidepressants</b>	<b>Anxiolytic/ Hypnotics</b>	<b>Antiepileptics</b>	<b>Antipsychotics</b>	<b>Dementia drugs</b>
<b>Number of participants</b>	27	21	19	31	3
<b>Percentage of participants</b>	34%	27%	24%	39%	4%

The association between the prescription of these groups of drugs and the groups following the first assessment was analysed using Fishers exact test owing to the small numbers in each group

*Table3.62 Analysis of antidepressant drug prescription in groups*

	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Prescribed antidepressants</b>	5	11	11	27
<b>Not prescribed antidepressants</b>	8	15	29	52

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	1.663	0.426
<b>Fisher's exact test</b>	1.748	0.426

There were no statistically significant associations demonstrated between those prescribed antidepressant drugs and the groups following the initial assessment.

*Table 3.63 Analysis of anxiolytic/hypnotic drug prescription in groups*

	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Prescribed Anxiolytic/hypnotic</b>	2	8	12	22
<b>Not prescribed Anxiolytic/hypnotic</b>	11	18	28	57

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	1.208	0.593
<b>Fisher's exact test</b>	1.115	0.593

There were no statistically significant associations demonstrated between those prescribed anxiolytic/hypnotic drugs and the groups following the initial assessment.

*Table 3.64 Analysis of antiepileptic drug prescription in groups*

	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Prescribed Antiepileptic</b>	2	4	13	19
<b>Not prescribed Antiepileptic</b>	11	22	27	60

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	3.167	0.220
<b>Fisher's exact test</b>	2.868	0.220

There were no statistically significant associations demonstrated between those prescribed antiepileptic drugs and the groups following the initial assessment.

*Table 3.65 Analysis of antipsychotic drug prescription in groups*

	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Prescribed Antipsychotic</b>	5	9	16	30
<b>Not prescribed Antipsychotic</b>	8	16	24	49

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	2.167	0.740
<b>Fisher's exact test</b>	2.329	0.800

There were no statistically significant associations demonstrated between those prescribed antipsychotic drugs and the groups following the initial assessment.

*Table 3.66 Analysis of dementia drug prescription in groups*

	<b>P group</b>	<b>FP group</b>	<b>NP group</b>	<b>Total</b>
<b>Prescribed dementia drug</b>	1	2	0	3
<b>Not prescribed dementia drug</b>	12	24	40	76

	<b>Value</b>	<b>Exact significance (2 sided)</b>
<b>Pearson Chi-Square</b>	3.198	0.155
<b>Fisher's exact test</b>	3.660	0.155

There were no statistically significant associations demonstrated between those prescribed dementia drugs and the groups following the initial assessment.

No statistically significant associations were therefore demonstrated between any of the central nervous system drugs and the groups following the first assessment.

### 3.6 Inter-rater reliability

An assessment of inter-rater reliability was carried out to test the hypothesis that PAINAD and DisDAT can reliably be used to identify pain. In each of the four homes a sample of assessments were repeated by a second researcher who was unaware of the scores given from the initial assessment. The repeat observations were all carried out within a week of the initial assessment having been carried out. The tool (DisDAT or PAINAD) completed by the second researcher was same the tool completed by the main researcher in the initial assessment. The level of agreement between the scores was analysed using the Kappa statistic.

*Table 3.67 Analysis of strength of agreement between researchers' scores*

	<b>Number of participants assessed twice</b>	<b>Kappa statistic</b>	<b>Weighted Kappa</b>	<b>Strength of agreement (Weighted Kappa)</b>
<b>DisDAT Rest</b>	13	0.414	0.343	Fair
<b>PAINAD Rest</b>	12	0.089	0.128	Poor
<b>DisDAT Eating</b>	11	-0.222	-0.262	Worse than by chance
<b>PAINAD Eating</b>	7	0.097	0	Worse than by chance
<b>DisDAT Intervention</b>	3	0	0	Worse than by chance
<b>PAINAD Intervention</b>	6	0	0.175	Poor

By using a weighted kappa statistic only the rest observation using the DisDAT showed fair agreement. The other observation agreements were either poor or worse than would have been expected by chance.

## **Chapter 4 ~ DISCUSSION**

### **4.1 Introduction**

The first objective of this research was to investigate the utility of a pain assessment and a distress assessment tool in a UK population with severe dementia. This objective was met by testing two hypotheses; that pain is common and under-recognised in this population and that such tools can reliably be used to identify pain.

From a study population of 79 participants, all with severe dementia, 16% were found to be in pain when assessed. Other studies, carried out in populations with moderate cognitive impairment, demonstrated that the proportion of patients with pain is between 32-62% [116-118]. Hence, the proportion of participants with pain in this study is less than might have been predicted. The reasons for this difference are discussed later.

Some participants had been identified by members of staff to have acutely painful conditions and treatment started. Other participants, who had developed painful conditions, had not been identified as having pain and were identified during the study. There were also several participants who were known to have potentially painful diagnoses whose pain was under-treated. Therefore, although pain was not as common as had been predicted by other research, there were instances where pain was under-recognised.



A third of the participants in the study scored above two in one of their assessments using the PAINAD tool but were not felt to be in pain. Therefore the PAINAD tool cannot be reliably used to differentiate pain from distress from other causes. Those who were felt to have pain all scored greater than zero using the DisDAT, therefore some of the behaviour listed for each participant was observed when they were in pain.

The second research objective was to demonstrate the ability of the tools to measure change in pain following change to the management regime, demonstrating that the tools are sensitive to change. There was a statistically significant change in both the PAINAD and DisDAT scores on intervention following change in management for pain. Therefore, both tools are sensitive to change.

The third objective was to assess the nature of distress that may produce a false positive result on a pain scale. The majority of the behaviour observed seemed to be caused by the participant not understanding what was happening, leading to either fear and anxiety or anger and frustration. Other causes included distress caused by other residents, boredom and sadness. The CMAI scores for the false positive group were significantly different compared to those obtained by participants in the P and NP groups. The pain assessment tool used in this study identified behaviour from a wide variety of causes, not just pain. The same may be true of other pain assessment tools.

The final objective was to examine the use of analgesia within nursing homes and in those identified as experiencing pain. Paracetamol was prescribed most frequently in all

the study homes, both as a regular prescription and as required. Those identified as having pain were managed either by non pharmacological methods or by prescribing regular analgesia using the WHO analgesia ladder. It was hypothesised that analgesia prescribing was inadequate for those with severe dementia who had pain. In this study almost half of those identified as having pain were already prescribed regular analgesia.

The research findings are examined in greater detail in the chapters that follow. Initially, in section 2, I shall critique the design of the trial. In section 3, I shall compare the current research to previous research in the field. The results of the research will be discussed in section 4 to 12. In section 13, I shall discuss how the current research contributes to the principles of assessing and managing pain in dementia. Finally, in section 14, the implications of the research findings with regards to palliative care and dementia will be discussed.

## **4.2 Critique of trial design**

### **4.2.1 Recruitment**

The trial was specifically designed to assess good practice in pain management in severe dementia. Although some people with severe dementia are supported in their own homes, many live in nursing homes. In order to recruit sufficient numbers for the study, nursing homes were used as recruitment sites for the research. The homes were selected on the basis of having large numbers of residents with severe dementia and nursing staff who would be willing to participate in the study.

It is possible that nursing homes with larger numbers of residents with severe dementia have better skills in recognising pain or distress in those unable to communicate. However, it would have been more difficult to recruit sufficient numbers for the study if the research was spread across more sites. It is also possible that homes with nursing staff that were willing to participate may have had a greater interest in managing pain and distress in their residents, which could have influenced the results. As this study relied heavily on nursing staff completing background neuropsychological scales and completing the pain and distress assessment tools, it would have been virtually impossible to carry out the study without the assistance of the nursing home staff. Nursing homes within the NHS and private sector were selected so that the results were applicable to both types of home.

#### **4.2.2 Inclusions and Exclusions**

The level of dementia was assessed using the Clinical Dementia Rating scale (CDR) [134, 135] and those with a CDR score of 3 were deemed suitable for the research. The CDR has become one of the gold standards of global ratings of dementia in trials [237]. Other studies involving PAINAD have used the MMSE as a tool to assess levels of cognition, with a CDR score of three equating with 0-10 on the MMSE scale. The MMSE is susceptible to floor effects in those with severe dementia, as this group tend to score very few points [238]. In order to ask potential participants to complete the MMSE, assent would have had to be gained first. By completing the CDR with nursing staff, potential participants could be identified first and then assent gained for the study.

As all the participants had severe dementia, they were not able to give informed consent for the study and hence assent was gained from the next of kin. Five potential participants had no next of kin and had a solicitor appointed to manage their affairs. All the solicitors listed were contacted to ascertain if they were able to give assent for the study to ensure that those without a next of kin were not excluded. Unfortunately none of the solicitors involved felt able to give assent for the research. The Mental Capacity Act [56], section 32, was reviewed as to whether another person could be consulted with regards to giving assent. As the person needed to be interested in the participants' welfare but to have no connection with the project, it was difficult to identify such a person in all cases and therefore felt to be simpler to exclude this group of potential participants.

There were no other exclusion criteria used in this study. Other studies have used pain assessment tools specifically in those receiving medication for pain [3] or have excluded on the basis of recent admission to home or acute illness [183] or inability to report pain verbally [198]. By simply including all residents in a particular home with a CDR of 3, this research explored the utility of the assessment tools in all residents unable to report their pain reliably.

#### **4.2.3 Establishing dementia diagnosis**

Difficulties can arise in accurately ascertaining the underlying cause of a dementing illness; it is possible that this might have been the case for some of the study participants. Most study participants, however, had been reviewed by a consultant psychiatrist at some stage of their illness. It was presumed, therefore, that the underlying dementia diagnoses were reasonably accurate.

#### **4.2.4 Pain and distress tools**

There are numerous pain assessment tools designed for assessing pain that could have been used as part of the study. The criteria used for selecting suitable tools were that they had to be simple and easy to use, specifically designed for use in those with severe dementia and have some evidence of reliability and validity. Similar criteria were used by both Zwakhalen and Herr in their reviews of behavioural pain assessment tools for severe dementia [31, 183]. As discussed in the introduction, the Pain Assessment in Advanced Dementia (PAINAD) scale, adapted from DS-DAT and FLACC, has been found to be simple to understand and easy to use [31]. In the original study by Warden *et al* it was

found to have good inter-rater reliability but only moderate internal consistency [3]. Further work using the German version of the tool demonstrated good internal consistency and satisfactory retest reliability [118]. The PAINAD tool has been criticised for only covering common pain indicators and potentially ignoring more subtle pain indicators. In addition using a scale to score intensity of behaviours has not been substantiated in the literature [31] and work by Schuler *et al* demonstrated that the scale did not measure pain intensity [118]. However the PAINAD tool has been used to demonstrate **change** in levels of pain by administering the tool before and after PRN analgesic medication was given. The ability to identify change in pain following treatment has not been evaluated in other pain assessment tools.

The reviews of behavioural assessment tools by Hadjistavropoulos and Herr both concluded that no current tool could be recommended for adoption into generalised practice [31, 170]. Two of the main criticisms of the current behavioural pain tools were that “patient’s pain responses can be unique” and “research has not yet established the sensitivity of presence of individual behaviours as indicators of pain” [31]. The second assessment tool was selected to evaluate whether these concerns could be addressed by adopting a different approach.

The Disability Distress Assessment Tool (DisDAT) was developed to document the wide range of signs and behaviours of distress of people with intellectual disabilities. By completing a list of distress and contentment behaviours for the specific person, the tool could be tailored specifically to the person, thus recognising their specific behavioural

signs. In addition, labelling the behaviours observed as behaviours of distress rather than pain acknowledges the lack of evidence that there are specific behaviours that indicate pain. The cause of the behaviours of distress could be pain, but equally could be due to fear or anger or other negative emotions. The tool is not designed to be a scoring tool as it was felt that it was not possible to put numerical values onto behaviours, however the tool can be used with monitoring sheets in order monitor change in the behaviours observed. Carers who have used the tool have found that it is simple and easy to use [4]. Although the tool was originally designed to be used for people with learning disability who were unable to communicate, it was felt that the tool would be suitable for those with severe dementia. There are no published studies using this tool in elderly people with dementia, this is one of the first studies to use the tool in this group. As the DisDAT is not a scored tool it is difficult to establish its psychometric properties, however work is currently on-going in this area.

#### **4.2.5 Assessment method**

It is argued that establishing validity for any pain or distress tool for use in those with severe dementia is very difficult as there is no gold standard with which to compare the tools [31, 170]. Other pain assessment tools use the patients self-report as the gold standard with which they are compared. Those with severe dementia, who have communication difficulties, cannot provide this gold standard; hence deciding whether a tool does measure pain is very difficult. Using pain tools during specific situations, typically felt to be painful, is a method that has been employed by several research teams [121, 183, 200]. This technique can be problematic as there may equally be other

negative emotions associated with the situation, particularly if the person does not comprehend the situation, owing to cognitive impairment. There may be associated fear or confusion as to what is happening, or anger at what is being done, all of which might be captured by the pain tool. It was therefore decided that using these tools in routine care, in order to try and identify pain, would be the initial method to assess utility. If pain was found during the routine care and treated, it was decided to assess whether the tools were able to measure that change. In these two ways the usefulness of the tools as part of care in those with severe dementia could be assessed.

The observations took place at three different times in a participants' day, at rest, during a meal and during intervention. Other studies, as discussed previously, have used observations purely during intervention. Although a proportion of pain experienced may be musculoskeletal in nature and hence movement related, observing during other times in the day will help in capturing non-movement related pain. The original study by Warden *et al* used observations at three separate times, at rest, during a pleasant activity and during a potentially unpleasant activity such as toileting or transfers [3]. The original research plan was to use these three times; however, it became apparent that defining a period of pleasant activity for each participant in the study was going to be difficult. It was therefore decided that participants would instead be observed whilst eating a meal. It was felt that this may help to identify pain during chewing or swallowing.

The participants were observed for approximately five minutes during each observation. Although observing for longer periods would allow more time for behaviours to be noted,



it was felt that this could potentially become intrusive and therefore distressing to the participant. It was also felt to be important that the observation time frame could be replicated by nursing staff during their every day practice. Other research has asked for staff to recall behaviours over a much longer time frame [198]; however, this may be subject to recall bias, rather than staff documenting what they had just witnessed. Some research studies have videoed participants for short periods of time, which may have advantages in allowing inter-rater reliability to be accurately addressed. It was felt, however, that fewer relatives would be happy to give assent for this to be carried out, particularly the recording of intimate care. Video taping was carried out in the study by Zwakhalen *et al* [183], but a quarter of those who originally consented to the study refused to participate further.

The two assessment tools were both used at each of the observations. The behaviours for the DisDAT had been generated for the participant by asking at least two of the nursing staff involved in their care to complete the scale. This was in recognition that different members of staff may pick up different behaviours of distress, as discussed in the original research by Regnard *et al* [4]. At the time of assent being given, each participant was given a randomly assigned number. This was used to decide which tool the nurse or researcher used during the observation. It was felt to be important that both tools were used equally by both nursing staff and the researcher, so that it could be established that both could be used successfully by nursing home staff. Although both tools could have been completed by both nursing staff and the researcher during each observation, it was felt that this could affect how accurately the tools were completed.

It is possible that my presence in the participants' room during the observation may have affected the behaviours seen. It is difficult to know if having an observer present whilst routine care was taking place may have changed how the nursing staff carried out that care, with more time perhaps being given than would normally have been the case. It was always stressed prior to the observation that the purpose of the research was to assess the behaviours seen during the time of intervention and not the work of the nursing staff. If the research project prompted the staff to think more carefully about how routine care was given, this would be of benefit to the participant. In which case, this might in part explain the lower than expected prevalence of pain. Against this, however, is the number of participants who were felt to be distressed from reasons other than pain. An advantage of being in each particular home frequently for several months was that staff became accustomed to my presence as a researcher.

Another potential concern was that my presence in the room whilst care was being given could be distressing to the participant. Prior to the observation taking place the nursing staff were told that if they felt that my presence in the room was precipitating distress then they would alert me and I would simply leave the room. One way of avoiding these biases would be simply to ask the nursing staff to complete the tools. It was, however, necessary for me to be present in order to evaluate what had provoked the behaviours observed and begin to assess what the underlying cause for the behaviours might be.

#### **4.2.6 Establishing outcomes**

It is possible that not all episodes of pain were correctly identified. Without a gold standard (which would normally be self-report) it is impossible to be 100% certain that all behaviours were accurately interpreted. The decision about whether or not a participant's behaviour indicated the presence of pain was made from the observation as well as information from other sources. This included review of medical, psychiatric and nursing notes, physical examination and repeat observations if necessary, as outlined in the methods. Although this assessment can not be termed a gold standard, it was as thorough as could be expected in routine care.

As described in the methods, the false positive group was defined using the PAINAD scale. It was important to decide which participants without pain should be assessed further and the original data from Warden's study [3], the study by Leong *et al* [198], as well as work regarding VAS [230] suggested that those scoring above two out of ten potentially had significant behavioural markers of a negative emotion. The false positive group has been defined in this way uniquely in this study. The false positive group cannot be described as a control group to compare with the pain group. The false positive group demonstrated behaviours of distress from causes other than pain and changes were made to reduce their distress, but not as part of the research. In order to have a true control group, a group of participants with pain would need to be identified and reassessed without changes made to the management of their pain. This would be unethical; hence a true control group was not created for the study.

As described in the methods, a second researcher was used to assess inter-rater reliability. Although to provide true inter-rater reliability the raters should be observing at exactly the same time, this was difficult to achieve owing to the work schedules of both researchers. In addition it was felt to be too intrusive to have more people observing intimate care. It was, however, felt to be important to gain some measure of inter-rater reliability of the two tools.

### **4.3 Comparison with previously published trials**

The PAINAD scale was first published in 2003 by Warden *et al* [3]. When the current research study commenced, there had not been further published studies using PAINAD to assess pain. Since 2006, six studies have been published (the study by Gibson *et al* in 2004 [196] was not published in a peer reviewed journal). These have been carried out mainly in nursing homes around the world; however none has taken place in the UK. The current research is the first to use PAINAD in UK nursing homes.

Other work, as discussed earlier [152, 160], has demonstrated that self-report scales can be reliably used in those with mild to moderate dementia. These studies have also shown that self report scales are less successful for those with severe dementia, hence using behavioural assessment scales seems a sensible approach. Out of the published research to date, only the original study by Warden *et al* [3] solely used participants with severe dementia. The participants in the Leong study [198] had moderate to severe dementia but they were able to answer questions regarding their pain. The studies by Gibson, Zwakhalen and Schuler [118, 183, 196] all had participants with severe dementia, but

also contained participants with mild to moderate dementia. The participants in the research conducted by Basler *et al* [229] were verbally non-communicative and had dementia, however, owing to the original study being published in German, it is unclear how this was assessed.

The previous studies involved varying numbers of participants. The mean number of participants from other studies using PAINAD was 77, which compares well with the 79 participants in the current research. Most other studies used nursing staff to complete the scale, in common with this research. In addition, the majority of other studies used the PAINAD tool in conjunction with another pain assessment tool to provide a comparison. This research used a distress assessment tool, DisDAT to provide a comparison. As DisDAT has not previously been used with elderly participants with dementia, there are no other research trials with which to provide a comparison. No previous studies, however, have used PAINAD in conjunction with a distress assessment tool.

The method of observation varied between the previous studies. In the Zwakhalen study, observations were carried before and during influenza inoculations as a painful event [183]. Gibson, Schuler and Basler all carried out observations at times of routine care and movement [118, 196, 229]. Leong asked the nursing staff to complete the PAINAD reflecting on the participants' pain behaviour over the previous week [198]; it is therefore possible that some behaviours were forgotten. The study by Warden *et al* used three different observation times: no stimulation, rest or pleasant activity and an unpleasant event [3]. Although a proportion of pain experienced by elderly participants with

dementia may be musculoskeletal in nature, it is possible to have pain during other times of the day. This approach was, therefore, adopted in this research to give a broader view of the participants' pain and not solely focussing on specific painful events or movement related pain.

Only two previous studies have looked at the effects of the PAINAD scores after treating pain. The study by Warden *et al* also involved a second cohort of 25 participants and collected data on their PAINAD scores before and after administering as required pain medication. They demonstrated a significant improvement in PAINAD scores. Basler involved 12 participants with pain who had their PAINAD scores recorded before and after commencing analgesia [229]. They reported diminished pain behaviour two hours after commencing medication. Again, as the original paper was published in German, it is difficult to know how significant the change in scores was. The current research involves 13 participants who have been identified as having pain and commenced on a management strategy for their pain. In common with the Warden and Basler studies, an improvement in PAINAD scores was seen on treatment of pain.

Other studies have questioned the ability of PAINAD solely to identify pain. The original study by Warden discusses the possibility that alternative causes of the indicators included in the PAINAD scale have to be excluded, such as anxiety, resistiveness to care or negative emotions. This is highlighted in many of the questionnaire comments in the study carried out by van Iersel *et al* [201], where carers were concerned that some of the behaviours seen were caused by fear, anger or loneliness. Unlike the present study, none

of the previous studies has attempted to quantify the extent to which PAINAD scores might reflect reasons other than pain. Schuler *et al* [118] used the Neuropsychiatric Inventory and the Apathy Evaluation Scale to ascertain if the PAINAD was only measuring pain. There was no significant correlation between these scales and PAINAD scores in those with pain; they concluded that PAINAD measures a psychological construct other than those measured by the two scales. However, as demonstrated in the current work, there may be a wide variety of causes for the behaviour seen and simply collating these all in a broad scale such as the NPI may lead to the importance of the different causes being lost. It is also worth noting that in Schuler *et al*, those felt not to be in pain did not have a PAINAD score of zero, again suggesting that the PAINAD tool may identify behaviour with causes other than pain.

The previously published research using PAINAD is summarised in the table over leaf.

<b>Research study</b>	<b>Warden <i>et al</i> 2003 [3]</b>	<b>Leong <i>et al</i> 2006 [198]</b>	<b>Van Iersel <i>et al</i> 2006 [201]</b>	<b>Zwakhalen <i>et al</i> 2006 [183]</b>	<b>Gibson <i>et al</i> 2004 [196]</b>	<b>Hutchison <i>et al</i> 2006 [200]</b>	<b>Schuler <i>et al</i> 2007 [118]</b>	<b>Basler <i>et al</i> 2006 [229] (English abstract, German paper)</b>
<b>No of participants</b>	19 in initial study, 25 in intervention study	88	157	128	80	27	99	12
<b>Degree of cognitive impairment</b>	Mean MMSE of 2.8 +/- 4.5	Moderate to severe dementia, able to answer questions about pain	Not documented	47% had severe or very severe cognitive impairment	Mean MMSE of 13.9 +/- 8.2	76% diagnosed with dementia, 23.6% had MMSE < 25	Mean MMSE of 12.1 +/- 9.7	Verbally non communicative patients with dementia (not clear how this was assessed)
<b>Scales used</b>	PAINAD, VAS, DS-DAT	PAINAD, VDS completed by nurse and participant	PAINAD and Abbey	PAINAD, PACSLAC, Doloplus-2	PAINAD, abbey, verbal and numeric BPI, informant BPI	PAINAD (with a control group with a MMSE > 25 rated using a VAS)	VDS completed by nurses prior to observation, then PAINAD	PAINAD
<b>Tool completers</b>	Research team	Nursing staff	Nursing staff	Nursing staff	Nursing staff	Nursing and medical staff	Nursing staff	Nursing staff
<b>Setting</b>	Dementia special care unit, USA	Nursing homes in Singapore	Nursing homes in Belgium	Nursing homes in Holland	Nursing homes in Australia	Post surgery in USA	Nursing homes in Germany	Geriatric clinic in Germany



<b>Research study</b>	<b>Warden <i>et al</i> 2003</b>	<b>Leong <i>et al</i> 2006</b>	<b>Van Iersel <i>et al</i> 2006</b>	<b>Zwakhalen <i>et al</i> 2006</b>	<b>Gibson <i>et al</i> 2004</b>	<b>Hutchison <i>et al</i> 2006</b>	<b>Schuler <i>et al</i> 2007</b>	<b>Basler <i>et al</i> 2006 (English abstract, German paper)</b>
<b>Scales repeated?</b>	Yes after PRN meds given in the second part of the study	No	No	Scales completed before and during influenza vaccination	Scales completed at rest and on movement	No	Scales completed after 2 mins observation, carried out morning and evening	Given analgesics after 1 <sup>st</sup> observation. PAINAD repeated after treatment stopped in 5 patients
<b>Outcomes</b>	Good inter-rater reliability, moderate internal consistency. Reduction of PAINAD scores after medication in 2 <sup>nd</sup> part of study	PAINAD correlated well with NRPS but both correlated poorly with SRPS	52% of nursing staff felt PAINAD was useful to judge pain. Concerns about specific items and ability to measure pain not discomfort	PAINAD showed good homogeneity, reliability and validity. PACSLAC found to be more useful by care providers	PAINAD showed fair inter-rater reliability, very good internal consistency but low concordance on movement with informant BPI	More analgesics given to group assessed using PAINAD, unclear why those without cognitive impairment were not asked about their pain	39 had pain. Good internal consistency, inter-rater reliability and retest reliability. PAINAD scores higher in those with pain, but tool did not measure intensity	PAINAD scores remained low only for those still on treatment

*Table 4.1 Previously published research using PAINAD*

To summarise, the current work is the first research study of using the PAINAD tool in UK nursing homes and the first to compare it with a distress tool. The numbers of participants in the study were comparable to other studies and used nursing staff to complete the scales. Unlike some other studies, the participants all had severe dementia and were not just assessed at times of intervention, but at other times during the day. Few studies have examined the effect of PAINAD scores on using analgesia and similar results were obtained in this work to those in other such studies. Although other studies have suggested that the PAINAD tool may identify behaviours due to reasons other than pain, none have to date examined how frequently this may occur or what the reasons for that behaviour might be. The sensitivity and specificity of the PAINAD tool has not been described in previously published studies. By using a PAINAD score of above two to be of relevance, the current work has demonstrated that PAINAD is a sensitive tool with regards to identifying pain, but has a specificity of 61%. Although several aspects of the relative utility of both PAINAD and DisDAT has been demonstrated in this pilot study, such as the ability to demonstrate change in scores with treatment of pain, further work is necessary to explore the utility of the tools as part of the management of those with severe dementia. This is discussed in more detail in section 5.5.

#### **4.4 Discussion of background data**

Of the 79 study participants, 72% were female. This percentage reflects UK data for dementia as detailed in the recent Kings College report of 2007, where the national ratio for dementia is approximately two women for every man affected [8]. This is due to higher mortality among men and higher age specific dementia prevalence in women. This effect is probably exaggerated in this study owing to the study specifically including those with severe dementia. Similar ratios were seen in other research involving PAINAD including the work by Zwakhalen and van Iersel [183, 201].

In the current research, 53.2% of participants had Alzheimer's disease, 29.1% had vascular dementia and 11.4% had mixed dementia. The Kings College report [8] estimated that around 62% of people with dementia have Alzheimer's disease, a higher proportion than our study population. In addition the report found that vascular and mixed dementia accounted for around 27% of cases, the current study population had a much greater proportion of vascular and mixed dementia. There are several reasons why this may have occurred. The vast majority of study participants had been given a diagnosis by a consultant psychiatrist; whether this is true of all of the Kings College data is not clear. The rates of cardiovascular disease in the north east of England are higher than in many areas of the UK [239], which may explain the larger proportion of study participants with vascular or mixed dementia. The number of participants with Dementia with Lewy bodies (DLB) is fewer than might have been expected; the prevalence is usually thought to be just under 20% of dementia cases [13]. This may in part be due to the majority of participants being female, whereas DLB has a slight male excess [13,

240] . From other studies conducted using the PAINAD scale, only Zwakhalen *et al* [183] reported the dementia diagnoses of study participants, with 32% having Alzheimer's and 18.8% vascular dementia.

The mean age of participants in the current study was 81.9, with the Kings College data reporting that two thirds of those with dementia are aged 80 and over [8]. Other studies that have used PAINAD had participants whose mean ages ranged from 78 to 88 [3, 118, 183, 196, 200, 229].

The range of time since the participant was given a formal diagnosis of dementia is quite broad in this study, stretching from those who had only been given their diagnosis 15 months previously to those who had been diagnosed 16 years ago. This probably reflects the differing prognoses with different types of dementia. Those with Alzheimer's disease have a variable prognosis of between 2 to 16 years (24 to 192 months), whereas those with vascular dementia have a shorter prognosis of around 5 years (60 months) [13]. In addition the participants had been resident in their current home from as little as 2 months up to over 9 years. It is possible that those who had only recently been admitted to the home might have been harder to assess, as the staff may not know them as well as those who had been resident in the home for a longer period of time. Having a broad range of times since the participants were admitted allows for this potential variability.

In summary, the participants in the study were matched for age and sex to both national reports on dementia demographics and other similar research studies. There was a wide

range of both time since diagnosis and time since admitted to home, hence the participants would be representative of many of those with severe dementia. It is difficult to know whether having a greater proportion of participants with vascular dementia has affected the results obtained. Much of the research regarding how neuropathology of the dementing process may affect the pain experience has centred on Alzheimer's disease, with less research specifically focussing on vascular dementia. It has been hypothesised that both the medial and lateral pain pathways could be affected by infarcts in vascular dementia, possibly reducing the pain experience [131]. As these infarcts can potentially cause central post-stroke pain, it has been postulated that those with vascular dementia may experience more pain. This has been suggested by Scherder *et al* [142] in a small study. However, not all of the participants had CT or MRI evidence of vascular disease. A more recent study [143] looked at the relationship between cardiovascular risk factors and pain in people with cognitive impairment but left many unanswered questions regarding the role of these risk factors. With a lack of conclusive evidence surrounding whether any type of dementia either reduces or increases the pain experience, it is not possible to conclude whether the proportions of the various types of dementia could have influenced the eventual outcomes.

## **4.5 Discussion of the background neuropsychiatric scales**

### **4.5.1 Depression**

The study participants had a median CSDD score of 5, with scores below 6 usually indicating an absence of significant depressive symptoms. There were, however, 10 participants (12.6%) who had a CSDD score of above 10 which may indicate major depression. Research carried out by Ballard *et al* [241] examined the prevalence of depression in those with Alzheimer's disease and vascular dementia, also utilising the CSDD. For severe dementia (MMSE < 10), 12.5% of their study population had scores indicating major depression, which compares well with the level of major depression identified in the current research participants.

### **4.5.2 Dependency**

The original work by Pattie and Gilleard categorised those with a CAPE-BRS score of greater than 18 as being of maximum dependency due to severe impairment and those with scores between 13 and 17 being high dependency [227]. Other studies using CAPE-BRS with participants with severe dementia have demonstrated a mean score between 21 and 22 [242]. The majority of the participants in the study could be categorised as being either high or maximum dependency according to their CAPE-BRS scores. Only three participants scored less than 13, which would indicate medium dependency. The level of dependency of the participants is reflected by the level of care they required as all were resident in either EMI or ESMI nursing homes.

### **4.5.3 Psychopathology**

The mean NPI score for the study participants was 14.5. A study carried out in Belfast of 435 patients with probable Alzheimer's disease used the NPI to examine levels of behavioural and psychological symptoms [243]. The group examined had a mean MMSE of 13 and a Functional Assessment Staging score of 6 (with 6 or 7 regarded as indicating severe dementia). The mean total NPI score of this study population was 41, considerably higher than the mean scores for the current research group.

There are several potential reasons for the differences between the two populations. Although the MMSE was not measured in the current research, it is likely that the mean MMSE would be less than 13 as all the participants in the current research had a CDR score of 3 (which is often equated with an MMSE of less than 10). It is possible that neuropsychiatric symptoms are more obvious in the moderate stages of dementia and become less obvious in the more severe stages, as in the current population under study. In addition, only 6% of the participants in the Belfast study were resident in an EMI unit/ward, with the majority living at home. It is possible that in more specialised units components of the NPI, such as night time behaviours or depression, would have been identified and managed and therefore less likely to produce a score on the NPI. Finally the participants from the Belfast study all had Alzheimer's disease, whereas the current study involved participants with a range of dementia diagnoses. These factors may all contribute to the differences seen between the mean NPI scores in the current research and a large recent study.

#### **4.5.4 Agitation**

The mean CMAI scores for the study participants was 52.2. A recent study of agitation using CMAI in 211 nursing home residents in Norway [244] found a mean total CMAI score of 42.7 in those with a Functional Assessment Staging score of 6 or 7. The paper discusses the reasons why levels of agitation are generally lower in Norwegian homes as the homes are smaller, have high staffing ratios and utilise person centred care techniques. There are few other studies looking at agitation levels using the CMAI. Most of these are of those with dementia living in the community or are drug trials where those selected are noted to have high levels of agitation. It is difficult therefore to compare the agitation levels seen in the current study population to other studies utilising the CMAI.

In summary, the level of depression amongst the study participants was comparable to other research of depression in dementia. The level of dependency was in keeping with the placement policy for those with advanced dementia. Levels of psychopathology were lower than other studies; however it was difficult to identify studies carried out on similar populations. Levels of agitation were slightly higher than in a similar population studied in Norway. The lower psychopathology and higher agitation levels of the population studied may have influenced results obtained at one month; however without having immediately comparable studies, it is difficult to comment on the magnitude of this effect.



#### **4.6 Discussion of the first assessment results**

From the 79 study participants, 13 (16%) were felt to be in pain during at least one of the three observations. The remaining 66 participants who were not felt to be in pain were subdivided as described previously, with 26 participants (33%) scoring above 2 on the PAINAD scale in at least one of the three observations. The level of pain detected by carrying out the observation was not as high as was originally anticipated when the study was designed. Research involving elderly nursing home residents has suggested that between 45-80% will describe substantial pain [28-30]. Although it is clearly difficult to define the proportion of those with severe dementia who experience pain, extrapolating from research carried out from those with moderate cognitive impairment suggests that between 32-62% [116-118] will experience pain. This is clearly more than the proportion that was identified by the current research study. There are several reasons why this may have occurred.

##### **1. The observation time frame was too brief**

Each observation, whether at rest, during a meal time or during intervention, lasted approximately five minutes. Occasionally the observation period was longer; particularly during intervention as the nursing staff were only able complete the tools once the intervention was complete. Other studies have used observation times of two minutes [118, 183, 229], whereas Leong *et al* asked nursing staff to recall behaviours over a week [198]. Clearly if a participant is only observed for a short time frame such as five minutes, this leaves large periods of time where they are not observed as closely. There may be behaviours caused by pain that therefore simply go unnoticed. One alternative is

to observe a participant closely for a longer period of time; however this runs the risk of becoming intrusive and may provoke distress in the person being observed. Another possibility is to ask staff to recall behaviours observed over a time frame, similar to the method employed in Leong *et al.* This may be subject to recall bias and a more accurate record may be created by documenting immediately what has been observed. The five minute time frame was used in the original study by Warden *et al* [3] to strike a balance between being long enough to observe behaviour but not too long to become intrusive. It is acknowledged that in using three five minute observation times some behaviours occurring during the day (and therefore pain) may have been missed.

## 2. The dementing process affects the pain experience

There is evidence that the pain experience may be altered for those with severe dementia, which could potentially reduce the numbers of participants found to be in pain. As discussed in the introduction, the neuropathological changes that occur in Alzheimer's disease and vascular dementia have been postulated to affect pain pathways [130, 131]. Clinical evidence for an altered pain response to this has been provided by case reports [132] in Alzheimer's disease sufferers. There has also been research demonstrating a change in physiological parameters in response to acute pain stimuli [133, 136, 137] in those with Alzheimer's disease. The evidence for neuropathological changes affecting pathways has been challenged by recent work utilising fMRI techniques. This demonstrated that activity in both medial and lateral pathways was preserved in response to pain stimuli [141]. It is, therefore, difficult to say with certainty that dementia affects the pain experience in all sufferers. There may have been some participants within the

study sample who did experience pain in a different way to other participants; however it is impossible to know what proportion of the sample this might be.

### 3. Behavioural pain scales do not assess pain as accurately as self report methods

Both subjective (self report) and objective (behavioural assessment) approaches are used in the management of chronic pain. It has been suggested that self report cannot be replaced by pain behaviour observation [177] particularly as concordance between the two measures has been demonstrated to be either low or moderate [176-178]. It is possible that the different approaches constitute different but complementary components of the pain experience [177, 245]. In addition, patients do not always express pain behaviours in predictable ways [179]. The studies comparing behavioural assessment tools and self-report have principally involved chronic pain patients without cognitive impairment. The study carried out by Pautex *et al*, as discussed in the introduction, demonstrated that an observational pain assessment tool also correlated only moderately with self assessment in a group of patients with severe dementia who were able to report their pain [174]. In addition, Gibson *et al* demonstrated low to moderate levels of concordance between PAINAD and a self report scale (Brief Pain Inventory) when used with patients with severe dementia [196]. It is possible, therefore, that behavioural pain scales do not always identify pain as accurately as might be gained from self report. This may therefore explain some of the differences between the predicted levels of pain obtained by self report and those identified utilising behavioural techniques. In addition, although every effort was made to identify the cause of the behaviour correctly, it is possible that behaviour caused by pain was misinterpreted.

#### 4. Better pain assessment and management in the homes involved

The nursing homes had several weeks from agreeing to the study to the actual observations commencing, during which time assent was sought from the relatives of potential participants. There could have been more of a drive to assess and treat pain prior to the observations starting. However this seems unlikely as only 10 participants were on regular analgesia and very few had had this recently commenced. It is possible that those in the NHS ESMI home would have had greater access to medical input and potentially had pain managed more successfully prior to the research starting. In addition, two of the nursing homes (Cleveland Park and Appleby) had regular weekly GP input. Despite these differences between medical input in the homes, it was demonstrated that the place of residence was not significantly associated with the groups in which the participants were allocated following the initial assessment.

The most likely factors, therefore, leading to fewer participants being identified as being in pain were; the time frame for observation, the potential for dementia to affect the pain experience, the possibility that behavioural assessment methods may measure a different aspect of the pain experience than self report and the potential for the behaviour observed to be misinterpreted. It is difficult to be certain to what extent these factors influenced the levels of pain identified or if anything further could have been done to control for these issues. It is possible that other studies, that quantify levels of pain in those with dementia, were affected by these factors. For example, in the study by Schuler *et al*, some of the behaviour observed may have been misinterpreted as pain behaviour by nursing staff, leading to higher levels of pain being recorded [118].

It is worth highlighting that although participants were assigned to the groups on the basis of the first assessment, this did not necessarily indicate that those not identified as having pain initially could not develop painful conditions at a later date. An example of this occurring has been provided in clinical vignette 8.

## **4.7 Discussion of the associations with groups**

### **4.7.1 Sex**

No significant association was found between the assigned groups following the first assessment and the sex of the participant. Epidemiological studies demonstrate that women compared to men will report more severe pain intensity, more frequent pain, pain in more areas of the body and pain of longer duration [246]. There are many painful conditions that are more common in women than men (such as head and neck pain and rheumatoid arthritis) that may account for the differences as well as an increased willingness of women to report pain and seek healthcare. The inclusion criteria for the study participants in the current research included being unable to communicate verbally in a reliable or consistent manner. The study participants, by definition, were unable to report their pain therefore potentially leading to the gender differences being unapparent. No other studies have specifically addressed whether gender differences in pain may be different in severe dementia.

### **4.7.2 Dementia diagnosis**

There was no significant association found between the assigned groups following the first assessment and the dementia diagnosis of the participant. From examining table 3.9 on p 139 regarding dementia diagnosis; it would appear that the proportion of those with vascular dementia with pain was greater than the proportion of those with Alzheimer's disease who had pain; however this was not statistically significant.

As discussed previously, the current published research regarding how dementia diagnoses may affect the pain experience is not fully conclusive, making it impractical to draw firm conclusions for all those suffering from dementia. This factor, coupled with the current research finding of no statistically significant associations between pain and specific dementia diagnoses, highlights the importance of assessing pain in all those with dementia, whatever their underlying diagnosis might be.

#### **4.7.3 Place of residence**

There was no significant association found between the assigned groups following the first assessment and the place of residence of the participant. All the homes involved in the study were located in the same geographical area and had large numbers of residents with severe dementia. A potential influence on pain management within the homes could have been the level of medical input within the homes. Tynemouth Court is a NHS ESMI unit with regular consultant psychiatrist review as well as input by junior medical staff. Both Cleveland Park and Appleby homes have weekly GP input from a local practice with most residents transferred to this GP's care. The participants at Willow Court are seen by their GP when requested to do so by medical staff at the home. Despite these differences regarding medical input, this does not seem to have affected the number of participants from each home that were found to have pain.

In summary, no statistically significant associations have been demonstrated between these categorical variables and the groups assigned following the first assessment. The current research has not demonstrated that pain is more commonly seen in a particular

sex or for a particular dementia diagnosis. In addition, despite different homes being involved in the study, pain was not identified more frequently in any particular home. The lack of specific associations between these variables and pain being identified suggests that it is not possible to target a particular group when trying to identify pain. It is worth highlighting that some of the numbers in each subgroup for certain variables were quite small. It is possible that with greater numbers of participants some associations may have been identified.

#### 4.7.4 Age

There was no significant association found between the assigned groups following the first assessment and the age of the participant. Studies examining the epidemiology of chronic pain in the community have demonstrated that age is a significant predictor of the presence of pain, with increasing proportions of people reporting chronic pain as they get older [247]. As discussed previously, numerous studies of elderly people have demonstrated prevalence of pain to be between 49% and 83% [30]. What is less clear is whether there is a difference between age groups within the cohort of patients who are elderly (often given as those over 65 years old). Several studies demonstrated that levels of pain are less with increasing age. The study by Won *et al* [103] highlighted that the presence of pain was lower amongst those aged over 85; there were also lower levels of reported cancer pain in the study by Bernabei *et al* [29] in the same age group. These findings were also borne out by a recent study by Zyczkowska *et al* [248] who demonstrated that the mean reported pain score in elderly nursing home residents was lower with each 5 year increment above the age of 65. Research carried out in Sweden by



Jakobsson *et al* [249], however, demonstrated that pain was more common with higher age with the greatest prevalence of pain reported by those over 90. All the participants from these studies were able to give a report of their pain, unlike the participants in the current research. It is unclear whether levels of pain do alter with increasing age if people are unable to report their pain; this was not demonstrated by the current research.

#### **4.7.5 Time since diagnosis**

There was no association found between the length of time since the diagnosis of dementia had been made and the groups following the first assessment. The mean time since diagnosis was much less in the pain group than the other groups, however this was not statistically significant. As dementia progresses, potentially painful conditions may develop. Weight loss is frequently seen in advanced dementia that may lead to increased pressure damage. Loss of mobility may lead to increased falls and increased risk of fractures. Recurrent infections, that may be painful, are also more common [16, 67]. It could be hypothesised therefore that dementia becomes more painful as the condition progresses; however this was not seen in the current research. This may be because the research was carried out in EMI/ESMI homes where these potential complications of the condition are well recognised and efforts therefore made to avoid them occurring.

#### **4.7.6 Time since admission**

Again there was no significant association with the length of time that the participants had been resident in their current home and the groups following the first assessment. The mean and median times since admission were much less for the false positive group than

the other two groups; however this was not statistically significant. It is possible that those who had been more recently admitted were less settled in their surroundings potentially causing more agitation. It is also possible that with some participants only being resident in the home for a short period of time, the staff may have had less opportunity to develop strategies for dealing with this agitation. These factors may explain some the differences between the groups.

This study has, therefore, not demonstrated an association between these continuous variables and the groups assigned following the first observations. The current evidence regarding the effect of age on levels of pain for those over 65 is inconclusive and an association between age and pain was not demonstrated by the current research. Although there are reasons why dementia may become increasingly painful as the disease progresses, this was not demonstrated by the research. Finally, although there were differences seen between the groups in terms of the length of time that a participant had been resident in a home, these differences were not found to be significant. Again, the lack of specific associations between these variables and pain being identified suggests that it is not possible to target a particular group when trying to identify pain.

#### **4.7.7 Background neuropsychiatric scales**

No significant association was found between the measures of depression, dependency and psychopathology (CSDD, CAPE-BRS and NPI) and the groups following the first assessment. Parmelee *et al* [150] demonstrated a strong association between pain and depression in nursing home residents, however all of the participants were able to report their pain and complete depression scales. There is little data regarding associations between pain and depression in those with severe dementia, presumably owing to the difficulties in measuring these parameters in people who are unable to communicate. It could be hypothesised, in those who are increasingly dependant, that there may be an increased frequency of painful complications of dementia, such as pressure damage. Although the median CAPE-BRS score was slightly greater in the pain group, this was not statistically significant. The NPI measures several variables including hallucinations, depression, irritability and aberrant motor behaviour. It could be presumed therefore that NPI scores may have been higher in the pain and false positive groups, rather than those who did not score highly on either the pain or distress scores. This was not seen in the results from the study participants. It is not obvious why there was not an association between depression, dependency and psychopathology and the groups as might have been predicted, but the small numbers in each group following the first assessment may have been a factor.

There was however an association between agitation and the groups following the first assessment. The CMAI scores obtained for those in the false positive group were significantly greater than those in the other groups. The false positive group exhibited

behaviours that can be associated with pain, but were not actually felt to be in pain. It is possible that these behaviours were behaviours associated with agitation, which is a common behavioural symptom in severe dementia [67]. The underlying causes for the behaviour observed are discussed in greater detail later in this chapter.

Therefore, although a significant association was not demonstrated between levels of depression, dependency and psychopathology in the groups following the initial assessment, a statistically significant association was demonstrated between agitation levels and those participants in the false positive group. This may suggest that the behaviours seen in the false positive group could have been behaviours that are often associated with agitation e.g. verbal aggression, restlessness.

#### **4.8 Discussion of the initial PAINAD scores**

Analysis of the mean initial PAINAD scores demonstrated a significant difference in the mean scores for the eating and intervention observations. Further analysis of the data demonstrated that the mean initial PAINAD score for the eating observation was significantly higher in the false positive group and for the intervention observation was significantly less in the no pain group.

From examining table 3.39 of underlying causes for behaviour for the false positive group it is possible to see that much of the behaviour that was observed occurred at meal times. This may explain why the scores on the PAINAD tool were higher for this group during this observation. There are numerous reasons why mealtimes can be distressing occasions; for example, if there are swallowing difficulties, dislike of food presented or upset caused by sitting in close proximity to others. Work carried out by Steele *et al* demonstrated that around 40% of nursing home residents will exhibit challenging behaviours during meal times [36]. In addition, other than the participant who had toothache, none of the causes of pain identified in the pain group (table 3.35 p159) would be particularly worse during the eating observation. These reasons may explain why the mean PAINAD scores on eating were significantly greater in the false positive group than the pain or no pain groups.

As the mean PAINAD score on intervention was significantly less in the no pain group, this may suggest that the PAINAD tool is able to differentiate when pain is **not** present to some extent during intervention. Although the mean PAINAD score on intervention was

higher in the pain group than the false positive group, this difference was not statistically significant ( $p = 0.066$ ). Obtaining a higher PAINAD score on intervention does not necessarily mean that someone is in pain, as opposed to being distressed for some other reason. It may mean that obtaining a low PAINAD score during intervention indicates that pain or distress from another cause is less likely. There was one participant, however, who only scored one on the PAINAD tool but was felt to be in pain. Therefore a low score does not always exclude the presence of pain.

There were no statistically significant differences demonstrated between the scores obtained at rest for any of the groups. There are two reasons why this may have occurred. Most of the pain identified in the pain group was musculoskeletal in origin and therefore may not have been painful whilst sitting at rest. A recent consensus statement regarding assessing pain in people with dementia recommended assessing pain during a movement based task, as it is more likely to identify an underlying pain problem [170]. Alternatively, the PAINAD tool might be less able to identify pain at rest, as opposed to pain on intervention.

In summary, significantly higher initial PAINAD scores were obtained for the false positive group during eating. As outlined above, meal times can be potentially distressing occasions. Significantly lower PAINAD scores were seen on intervention in the no pain group, suggesting that the PAINAD is a sensitive tool. As a significant difference was not demonstrated between initial false positive and pain scores from the intervention observation, this suggests that the PAINAD tool is not specific. No significant differences

were seen between the scores at rest, either because there was no pain or other distress seen at those times or because the tool was not able to identify relevant behaviour at the rest observations.

## **4.9 Discussion of the results from pain and false positive groups**

### **4.9.1 Pain group results**

#### **4.9.1.1 Causes of pain identified**

Table 3.35 on p160 demonstrates the underlying causes of the pain identified during the assessment and the strategies utilised to manage the pain. Two of the participants had pain owing to relatively acute events, one with cellulitis and a DVT and another with toothache. Both acute conditions had already been identified by the staff at the time of the initial assessment and a treatment plan made or already started. By the time that the assessment was repeated, both demonstrated an improvement on the tools. Another participant seemed to be in pain on having her nails cleaned but had no discomfort on examination of her hands or with movement during daily activity. It was decided that the pain was purely provoked by the procedure and the staff were alerted to the issue.

Most of the pain identified in the study was caused by chronic painful conditions. Many of the conditions were not new diagnoses, but were documented in the participants' notes. It is possible, therefore, that many had worsened over a period of time and this had not been identified. As discussed previously, the majority of chronic painful conditions were musculoskeletal in origin, mainly caused by either arthritis or the development of contractures. Articular joint pain, foot pain and leg pain are known to become more common with increasing age [250] and most of the pain identified in the current research was in these areas. Several of the participants were identified as having pain secondary to



a more chronic cause that had not been previously documented. Two participants became uncomfortable after sitting on hard surfaces for a period of time owing to weight loss. In identifying this issue, lasting tissue damage was potentially prevented. Another participant (AP 9) was identified as developing a contracture of her arm that had not previously been recognised.

Most of the pain identified was nociceptive in origin. The prevalence of neuropathic pain in the community is reported to be around 7-8% [251] and is associated with older age [252]. Around one in six of those with chronic pain have predominately pain of neuropathic origin [252], however none of those with chronic pain complaints in the current research had predominately neuropathic pain. This may partially be due to the small numbers (ten) of participants who were felt to be in pain from a chronic complaint, but may be due to potential difficulties in identifying pain of this origin in people with severe dementia. This is discussed in more detail in the section on analgesia below.

Although the numbers identified as having pain were small, some interesting patterns have emerged that may guide how pain and distress tools are used. It would seem that acute events have often already been identified by nursing staff, but slower onset new conditions (such as contractures) may be missed. In addition, those with chronic painful conditions may require repeat assessments to identify whether their conditions are worsening and their pain medication needs reviewing.

The study by Pickering *et al* [139] examined analgesic consumption for acute and chronic pain in those with and without cognitive impairment. They demonstrated similar levels of analgesic consumption in the two groups for acute pain events, but significantly less analgesia was consumed by the cognitively impaired group for chronic pain. These findings corroborate the current research findings that acute events are often more readily identified. The lack of analgesia consumed for chronic pain in Pickering *et al* may be partially due to altered experience of pain, but may also be due to the signs of worsening chronic pain being more subtle and more easily over-looked. It is possible that using pain or distress tools on a regular basis may prevent this occurring and may allow chronic painful events to be readily identified and managed.

#### **4.9.1.2 Management of the identified pain**

A variety of strategies were employed to manage the pain identified during the study. The participants with acutely painful events had both already had a treatment plan made or started. The treatment was specific to the underlying cause and analgesia was given as well. The chronic painful events were managed with a combination of non-pharmacological and pharmacological methods, depending on the underlying cause and the strategies that had already been tried. Those who became uncomfortable sitting on hard surfaces were managed by alerting the staff to the issue and by the use of pressure relieving strategies intervention. One participant became very tense and rigid during intervention, causing pain on movement, possibly because of anxiety. This was managed by a complementary therapist carrying out weekly massage to see if this would relieve some of the tension. There was a small reduction in the distress score using this strategy.

Other participants were started on regular analgesia. It was quickly realised that simply using PRN medication would be unsuccessful in managing the identified pain, since once the participants were in pain and had become distressed attempting to give them analgesia was very difficult. One strategy employed was to give analgesia prior to movement if the pain was associated with this activity. This was successful with one participant (AP6) who was prescribed regular analgesia, but was often uncomfortable on getting up first thing in the morning. His medication was, therefore, administered to him half an hour prior to getting up, which allowed him to be more comfortable once the analgesia had been absorbed. If the participants were not prescribed regular analgesia, giving PRN analgesia prior to movement was not always successful as times of movement were not always predictable. Most participants were therefore prescribed regular analgesia.

Three participants were started on regular paracetamol. These participants had either not been prescribed any analgesics previously or were prescribed PRN analgesia. They were therefore started on analgesia from the lowest step of the WHO analgesic ladder. One participant with musculoskeletal pain was already on regular paracetamol and as required topical NSAID gel (WC20). The NSAID gel was therefore given regularly. Another participant (CP19, see vignette 2b), who was prescribed immediate release tramadol, was changed to the slow release preparation. It was felt that his pain was worse in the morning, potentially because of the night time dose wearing off, and the slow release tramadol provided a more consistent level of pain relief. One participant was prescribed procyclidine (AP9), specifically for the increased tone in her arm, by her own GP; a reduction in her pain and distress scores on intervention was seen at one month.

In summary, the management strategy employed for the pain identified depended on the underlying cause of the pain and the management that had previously been tried, with both non-pharmacological and pharmacological strategies utilised. The pharmacological management was linked to the WHO analgesic ladder and was given regularly as difficulties were encountered using PRN analgesia.

#### **4.9.1.3 Background neuropsychiatric scales**

Once pain was identified and treatment commenced, the participants were reassessed initially by repeating the neuropsychiatric scales. This occurred at approximately one month after the initial neuropsychiatric scales were carried out. There was no significant change demonstrated in levels of depression, dependency, psychopathology or agitation after commencing treatment for pain. As discussed previously, a strong association has been demonstrated between depression and pain [150]. By treating pain effectively, levels of depression may also be reduced. This effect was not demonstrated by the current research, possibly as the time frame was too short to demonstrate changes in levels of depression. In addition no specific association between pain and depression was demonstrated in this research, therefore if the pain group was not particularly depressed to begin with; it seems less likely that significant changes in depression would be demonstrated.

One potential effect of treating pain might have been a change in the levels of dependency. It is possible that if someone is in less pain, then they are more able to participate in activities and hence would be less dependant. Although a statistically

significant change was not demonstrated, the results demonstrated a reduction in CAPE-BRS scores with a significance of  $p = 0.07$ .

No significant change was seen with the NPI scores. This tool is multidimensional in nature [70], assessing several areas of psychopathology. Not all of the areas assessed are specifically associated with pain such as hallucinations and delusions; however some of the areas assessed are associated with pain, such as depression and sleep disturbance. The combination of factors assessed using the NPI may have prevented a change in psychopathology being elicited.

Finally no significant change was demonstrated in levels of agitation following intervention for pain. The CMAI consists of a list of 29 agitated behaviours, a third of these behaviours appear on the PAINAD scale. It is possible that not all of the behaviours of the CMAI are associated with pain and therefore treating pain will not always reduce the behaviours identified using the CMAI. This could explain the lack of significant change in the agitation scores.

In summary, no significant change in the scores of the neuropsychiatric scales was seen after the tests were repeated. This is possibly due to the time frame being too short between carrying out the tests for a significant change to be demonstrated. In addition some of the areas measured by the scales may not be specifically associated with pain, hence they would be less likely to change following treatment of pain. It is worth highlighting that the group identified as having pain was relatively small, with only 13

participants. This may have reduced the ability of a significant change in the neuropsychiatric scores to be demonstrated.

#### **4.9.1.4 Assessment results (1 month and 3 month)**

A significant change in the scores of both the PAINAD and DisDAT scores was demonstrated on intervention following a change in treatment for pain. It is interesting to note that the significant change occurred solely on the intervention observation. The majority of the pain identified during the research was musculoskeletal in nature, hence more likely to be more apparent during intervention. As expected, therefore, treating the pain identified during intervention led to a significant reduction in scores during intervention. One potential conclusion could be that these tools are unable to identify change in pain occurring at rest or during other activities. The work by Zwakhalen *et al* demonstrated lower scores at the time of rest and suggested that it is harder to estimate a person's pain at rest [183]. However, as so few of the participants had pain identified in situations other than during intervention, it is impossible to reach firm conclusions regarding the ability of the tools to identify change in all types of pain.

The original study by Warden *et al* also demonstrated a significant change in PAINAD scores on giving as required medication for pain [3]. It is not clear, however, what the participants were doing at the time they were in pain and why they needed PRN medication. In the current research the assessment tools were not repeated immediately following analgesic provision, but were repeated simply during the same type of observation. This therefore demonstrates the ability of PAINAD to identify change in

pain in general rather than just following analgesic administration. The only other study examining the ability of PAINAD to identify a change in pain was published in German [229] and the English abstract does not provide information as to whether the change in PAINAD scores was statistically significant.

There has not been any research published to date regarding the ability of DisDAT to identify a change in pain following intervention. By using behaviours generated by the nursing staff for a particular person and recorded using a PACA type scale, it has been demonstrated that DisDAT can also identify change in levels of pain.

The participants were reassessed three months after the initial assessment. This was to evaluate whether the treatments that had been commenced were still effective or whether the pain had worsened over time. There were no statistically significant differences demonstrated between the scores obtained at the one month assessment and those obtained at the three month assessment. Although this could imply that repeating pain assessments frequently is not necessary to monitor pain control, it is worth noting that several participants had worsening scores and worsening pain at the time of the three month assessment (see Vignette 1b). These participants all had chronic pain problems, therefore this group may need more frequent reassessment of their pain. It is also possible that the underlying cause of acutely painful events could have resolved. Regular reassessment of those with pain is therefore important to evaluate whether treatment is still required or can be stopped.

By repeating the tools following a change in pain management, statistically significant differences were demonstrated in both the PAINAD and DisDAT scores on intervention. Therefore both scales are able to measure change in pain following change to management regime, fulfilling objective 2 of the research. There were no significant differences seen in the scores obtained at the three month assessment. It cannot be said, however, that this is the appropriate time for reassessment. Identifying a specific time for repeat pain assessments for all of those with pain is problematic, precisely because pains are different as are individuals.

#### **4.9.1.5 Issues highlighted by vignettes**

The case vignettes chosen for the pain group emphasise specific issues surrounding both the use of pain and distress tools and how pain is managed in this group. The first vignettes (1a and b) involve participants with pain from contracted limbs. They highlight how such tools can be useful in deciding whether a specific treatment has been beneficial, as the change in behaviour can be subtle. In addition they draw attention to the importance of repeating the assessments on a regular basis. For instance, in vignette 1b the participant's pain had worsened over a two month timeframe. It is difficult to be specific regarding how frequently a pain or distress tool should be repeated. As discussed previously, both those suffering with acute and chronic pain problems may require reassessment as the underlying cause may have worsened or may have resolved. The natural history of the underlying condition is, therefore, an important factor that needs to be considered, although this will vary from person to person. Setting individualised



timeframes for reassessment of pain once treatment is commenced may be the most sensible approach.

The second pair of case vignettes was chosen to demonstrate that the underlying cause for the behaviour observed is not always initially apparent. By repeat observation and carefully noting the initiating and resolving factors associated with the behaviours observed, the underlying causes were identified. In both cases there were other factors contributing to the observed behaviour, with anger and agitation in the first case and fear in the second. Several authors have highlighted that pain may be associated with other emotions, such as fear [141, 144], particularly if the person is unable to put their pain into context because of cognitive impairment. The complete resolution of the behaviour may not therefore be a realistic goal in all those with pain. This has also been highlighted in other published work regarding pain management in persons with cognitive impairment [180].

The vignette regarding WC 9 (2a) also demonstrates a difficult aspect of scoring the PAINAD tool. As there is no timeframe built into the tool, it can be difficult to decide whether a particular behaviour should be the main scoring behaviour within a specific domain. For example, if a participant's facial expression is mostly inexpressive during the observation, with a brief episode of frowning, it is difficult to know whether to score the facial expression for the behaviour that was present for the majority of the time, or the behaviour that might be due to pain. This problem occurred several times during

observations and it was decided to score for the behaviour that was present for the majority of the time.

Using a PACA scale to record the DisDAT behaviours allowed for some reflection of the amount of time a behaviour was present as the behaviours that dominated the observation were the highest scoring. It could, however, be argued that the length of time a behaviour is present is not necessarily a reflection of its importance. A brief episode of a certain behaviour may be an important indication of underlying pain that should not be overlooked. Observing people with dementia for a specific timeframe is used in other tools such as Dementia Care Mapping. This is an observational tool used to evaluate quality of care from the perspective of the person with dementia [253]. Mapping takes place over five minute periods, with the main events from the perspective of the person being recorded [254]. The validity and reliability of this approach has been established [253]. It is important, therefore, to try and reflect the importance of specific behaviours observed for that individual in the context that they occur.

The final pain group vignette was chosen to highlight how finding a suitable treatment for some participants was not always straightforward. As discussed previously, deciding on the underlying cause for a behaviour can be difficult; however, if pain is a possibility, a trial of analgesia may be of benefit. Unfortunately, despite attempting several different approaches with this participant, none was particularly successful as a trial of analgesia. It is worth emphasising that there are different strategies that can be tried in order to manage pain and what works for one person may not be suitable for another. Advice was

sought regarding this participant from the palliative care services for people with learning difficulties, as many of the issues surrounding taking analgesia are very similar in both people with learning difficulties and people with dementia. It was decided, however, that as the underlying cause for the behaviour seen in this participant was not clear, close observation should be employed rather than pursuing further analgesic strategies.

These vignettes, therefore, highlight many issues surrounding the use of pain or distress assessment tools and managing pain in those with severe dementia. They demonstrate how the tools can help with deciding whether a treatment has been of benefit and emphasise the need for regular reassessment. The vignettes also reveal the difficulties that can occur when deciding if pain is the cause of the behaviour observed, particularly when there are potentially several causes. They also highlight issues surrounding how long a behaviour should be observed for it to be relevant and therefore how much weight should be given to a specific behaviour. Finally, they show some of the challenges that may occur when selecting suitable pain relief strategies for those with severe dementia.

## **4.9.2 Results from the false positive group**

### **4.9.2.1 Background neuropsychiatric scales**

The background neuropsychiatric scales were repeated for the false positive group at approximately one month after they were originally carried out. The false positive group had all scored greater than two on the PAINAD scale during at least one of the three observations. The underlying cause of the behaviours seen at these observations was not felt to be pain. No specific interventions were suggested for the participants in this group; however there were changes in the way that some of the participants in this group were cared for. This was highlighted in the case vignettes and will be discussed in more detail later.

Without specific interventions being suggested for the group, it could be presumed that levels of depression, dependency, psychopathology or agitation would not change after one month. Statistical analysis of the repeated neuropsychological tests revealed no significant change in levels of depression, dependency or psychopathology. There was, however, a significant decrease in levels of agitation in the false positive group. There are several reasons why this might have occurred. Although specific interventions were not suggested for this group, there were some changes made to the way some of the participants were managed. This may have arisen from nursing staff becoming more aware of agitated behaviour of study participants because of the research and attempting different techniques to manage this behaviour. If this management was successful it may have contributed to the reduction in agitation levels. Although the participants'

medication was not documented at the 1 month assessment, changes may have been made that could have influenced the behaviour seen. Most participants in this group had their medication documented at the 3 month assessment. Some had had an increase in antipsychotic medication, although others had had similar medication stopped. The changes in medication for some participants may have affected levels of agitation. The reduction in levels of agitation may also be a reflection of the natural history of the symptom, as the behavioural and psychological symptoms of dementia may fluctuate during the course of the illness [255] and may resolve spontaneously [66].

In summary, no statistically significant change was seen in the levels of depression, dependency or psychopathology; however a significant change was seen in the agitation scores. This could have been caused by changes in management strategies by nursing staff, fluctuation in levels of agitation or natural resolution of agitated behaviour.

#### **4.9.2.2 Assessment results (1 month and 3 month)**

The observations were repeated for the false positive group at approximately one month after they had originally been carried out. There was a statistically significant change in scores for both the DisDAT and PAINAD scale at rest, with the scores being significantly less at one month. There was also a significant reduction in the PAINAD scores on intervention.

There are several possible reasons to explain the change in scores seen despite specific interventions not having been suggested. Some of the causes of the behaviour observed at

the initial observations were due to specific circumstances that occurred that day, such as participants being disturbed by other residents within the home. Although the repeat observations were carried out at the same times of the day as the initial observations, it is possible (and probable) that those specific events prompting the behaviour observed initially were not present at the time of the repeat observations. The scores were accordingly lower at the time of the repeat observation. It is unclear why a significant change was seen at rest, but it is worth highlighting that the period of rest usually occurred with the participant sitting in the main lounge, surrounded by most of the other residents in the home. The potential was therefore there for specific random events to occur, such as one resident being noisy and upsetting other residents, thus causing distress behaviours to be observed.

The PAINAD scores for both rest and intervention were significantly less at the time of the second observation. This may be due to the group being defined by the PAINAD score that they obtained following the first observation. As the group had high PAINAD scores by definition, a change in the PAINAD score may have been more likely than a change in their DisDAT score. As highlighted previously, some changes to management, both pharmacological and non-pharmacological were made for some of the participants of this group. This may also account for a reduction in scores. Finally, the underlying causes for the observed behaviour could be described as the behavioural and psychological symptoms of dementia (BPSD). As BPSD may fluctuate during the course of dementia [255], the changes seen may simply be a reflection of fluctuating symptoms. In addition, some symptoms may resolve spontaneously [66] without specific treatment.

The observations were also repeated three months after the initial assessments had been carried out. There were no significant differences seen in most of the assessments, other than the DisDAT rest observation. The three month assessment scores for this observation were significantly greater than those from the one month assessment. The reasons for this are not obviously apparent. An increase in behaviours signifying distress in the absence of major causes might suggest transient incidents. These would need to be explored at the time for particular individuals. Concerns could be raised that as changes were seen in the scores from the assessment tools in the false positive group, this calls into question the significance of the changes in scores seen in the pain group. It is worth highlighting that the false positive group cannot be considered as a control group to the pain group, as the false positive group was defined differently to the pain group. This causes difficulty in comparing the outcomes for the two groups.

Significant changes were therefore demonstrated in both the PAINAD and DisDAT scores at rest and the PAINAD scores on intervention for those in the false positive groups. The change in scores at rest may have been caused by the specific circumstances that provoked the behaviour from the initial observation not being present at the repeat observation. The change in PAINAD score on intervention could have been owing to changes in management made by nursing and medical staff, natural fluctuation of agitated behaviour and by the group being defined by the level of their PAINAD scores. Most of the scores had not changed significantly at the time of the three month assessment.

#### **4.9.2.3 Causes of behaviour observed and issues from vignettes**

Table 3.39 on p 170 and 171 lists the underlying causes for the observed behaviour. Approximately half of the participants in this group appeared not to understand what was going on around them. This is conveyed by vignettes 4a and b, with both participants unable to make sense of their situation. One participant reacted with fear and anxiety to the situation, whilst the other became angry and frustrated. These behaviours were identified on the PAINAD tool, leading to both participants scoring greater than two. Other causes of distress were also seen, such as distress emanating from the nursing home environment, as highlighted by vignettes 5a and b. As discussed previously, specific suggestions were not made for participants in this group; however there were occasions where changes to management were made. These included: specific carers working with certain participants to reduce anger; careful explanation to reduce anxiety; and the provision of quieter areas to reduce distress from the care environment. For other participants, the original cause of the behaviour resolved of its own accord, as highlighted by vignette 7. Despite the behaviour resolving, it was still important to attempt to identify what the underlying cause might have been. Finally, the cause of the distress might change, as highlighted by vignette 8, owing to a change in circumstances. This again demonstrates the importance of reassessment and revisiting what the causes of behaviour might be.

If the PAINAD score had been taken at face value, then the behaviour observed for these participants could have been incorrectly labelled as pain, leading to inappropriate



management. The PAINAD tool will clearly identify when something is wrong, as demonstrated by the scores obtained for the participants of both the pain and false positive groups. What the tool failed to do was to differentiate between when the cause of the behaviours seen was pain and when it was caused by something else. This is demonstrated further by the fact that significant differences in the initial PAINAD scores were not seen between the false positive and pain groups, other than during the eating observation. Hence simply identifying that something is wrong and that someone is distressed may be the first step in assessing pain. The second step would be to assess what the cause might be, with one of the possibilities being pain. This would prevent behaviour, from causes other than pain, being inappropriately labelled and managed. By careful evaluation of the antecedents of the behaviour, what stopped the behaviour and knowledge of medical and personal history, the cause of the behaviour can be identified often and suitable management strategies devised.

#### **4.9.3 Results from both P and FP groups**

Analysis was also carried out to assess whether the change between initial and 1 month DisDAT and PAINAD scores was similar in both the P and FP groups. No significant differences were demonstrated in the proportion by which the scores changed, other than the DisDAT score from the eating observation. This seems likely to be a type 1 error and may not be of consequence given there is no more rational explanation. Therefore the proportion by which the scores changed in each group was comparable, suggesting that the scales can identify change to a similar degree in both groups.

## **4.10 Discussion of the behaviours documented and observed**

### **4.10.1 DisDAT results**

From completing the DisDAT for the participants in the study, a large quantity of data has been collected regarding the behaviours of both contentment and distress that can be seen in persons with severe dementia. The results collected mainly focussed on the behaviours of distress, with 129 different behaviours being documented for 79 participants. Clearly, with such a wide variety of behaviours being recognised by nursing staff, it would be difficult to create a single assessment tool that would assess all these behaviours. The commonest identified behaviours of distress were not behaviours of distress for all participants. It has been argued that assessment scales should be matched to the patient, with the patient able to demonstrate all the behaviours by which they are being assessed [182]. Otherwise even using common behaviours, such as frowning, could lead to some patients being assessed using behaviours that they will not demonstrate, no matter how severe the distress.

In addition, 72 behaviours were unique behaviours only documented for one participant. The issue of the wide variation in behaviour seen and the unique nature of an individual's behaviour are discussed in the review of pain assessment tools by Herr *et al* [31]. They highlight that a patient's pain responses can be unique and that pain assessment tools should assess as broad a range of pain indicators as possible. Research carried out by Closs *et al.* [205] by interviewing nursing home staff about pain cues in 113 residents, identified an extensive range of cues including body movements, facial expressions,

verbal and vocal cues. This work discusses how both formal and informal carers are able to identify a variety of cues, but may identify different cues. In the current research at least two nursing staff were asked for their opinions when the DisDAT was completed.

Table 3.44 on p186 lists the 20 most common behaviours of distress identified by completing the DisDAT. Most of these behaviours are found on pain assessment tools but some, such as skin changes and looking startled or staring, would not have produced a score on the PAINAD tool. The distress behaviours that were observed during times of pain are discussed later. Although there were behaviours that were recognised more frequently than others, unique behaviours may be just as important. The original research by Regnard *et al.* [4] suggested that each patient has their own “language of distress” and focussing only on the common cues may risk ignoring important markers of distress.

Table 3.45 on p187 summarises the types of unique behaviour documented, with more detail on the unique behaviours given in table 3.46 on p188. The most common form of unique behaviour was speech, followed by habits and mannerisms. From the table 3.46, it is possible to see that some of the behaviours identified could quite easily be misinterpreted as not being associated with distress, such as rolling up trouser legs. Hence using the expert knowledge of nursing staff is vital in interpreting behaviour. Work carried out by Parke demonstrated that nursing staff who know their patients well are able to recognise change in behaviour and begin to evaluate what the change signifies [165]. Qualitative research by Regnard *et al.* highlighted that both professional and family carers felt that documenting behaviours of distress would help when a person was

transferred to other settings, such as to hospital, as those caring for the person may not be able to understand idiosyncratic behaviours [4].

In summary, a wide variety of behaviours was documented by completing the DisDAT for the study participants. Over half of the behaviours documented were only seen in one participant. The ability to recognise the meaning of the behaviour seen, often specific to the person, is vital in identifying distress.

#### **4.10.1.1 Correlations of number of behaviours of distress with background data**

Further analysis was carried out on the number of behaviours of distress that were documented for each person. As discussed previously, women, when compared to men, will report more severe pain intensity, more frequent pain, pain in more areas of the body and pain of longer duration [246]. There was, however, no association between the number of behaviours of distress identified and the sex of the participant. There were no significant differences between the number of behaviours identified by the staff from the four homes, which suggests that staff at each of the research sites were able to identify a range of behaviours for all their residents participating in the research. In addition the length of time that a participant had been resident in the home was not correlated to the number of behaviours of distress identified. Some participants had only been resident in a certain home for two months, yet nursing staff were able to discern behaviours of distress. This was also borne out in the study by Closs *et al.* [205], where again many staff had only known their residents for two months, yet were able to identify pain cues.

There was no significant association demonstrated between the dementia diagnosis and the number of behaviours of distress identified. However, it might be hypothesised that as the condition progresses the number of behaviours of distress identified might be less. This is partially predicted on the view that “challenging behaviour” slowly burns out as dementia progresses. Similarly, the repertoire of distress behaviours might also narrow. For example one participant, for whom only one behaviour of distress could be identified, died the day after the DisDAT was completed. However, on analysis of the data, a significant correlation between the number of behaviour of distress and time since diagnosis was not demonstrated ( $p = 0.085$ ). There was no significant association demonstrated either between the age of the participant or their analgesic prescription and the number of behaviours of distress.

#### **4.10.1.2 Correlations of number of behaviours of distress with background neuropsychiatric scales**

The potential correlations between the number of behaviours of distress and the background neuropsychiatric scales were assessed using Spearman’s rank correlation. This demonstrated a weak correlation between the CSDD scores and a moderate correlation between the CMAI and NPI scores and the number of behaviours of distress. This may be owing to the observable manifestations of depression, agitation and psychopathology being seen as behaviours of distress. Therefore, a participant known to be agitated may display a wider variety of behaviours of distress. The correlation between depression scores and the number of behaviours may be weaker as there may be less observable behaviour if someone is depressed, as opposed to if they are agitated. There

was no significant correlation demonstrated between the CAPE-BRS scores and the number of behaviours of distress. This suggests that however dependant a person may be, there will still be a range of behaviours of distress that may be recognised.

Therefore, for the background parameters that were measured in this research, no significant associations with the number of behaviours of distress were demonstrated. This suggests that a list of behaviours of distress can be identified for most elderly patients with severe dementia, regardless of many factors including dementia diagnosis, age, dependency or length of time in the home. The behaviours associated with depression, agitation and psychopathology may have led to the correlation seen between these variables and the number of behaviours of distress.

Table 3.50 on p193 lists the number of distress behaviours seen during the assessments where pain was felt to be present. It demonstrates that for all of these assessments, at least one distress behaviour was observed. Creating a list of distress behaviours for those unable to communicate their pain is therefore a useful method of recognising behaviour that may be caused by pain.

#### 4.10.2 PAINAD results

To investigate further the commonest scoring behaviours documented for the pain and false positive groups, the assessments that scored greater than two were collated for each group. In both groups, the breathing domain scored less than the other parameters. This was identified in the original work by Warden *et al* [3], who demonstrated that the reliability of the PAINAD tool could be improved by either deleting the breathing item or combining with the negative vocalisation item. They decided to retain breathing as a separate item as many patients with advanced dementia have intercurrent respiratory illnesses and as changes in respiration can be seen in acute pain. Whether intercurrent respiratory illnesses are always painful is debatable, hence this may not be a good reason to retain an item for a pain scale. Other published work utilising PAINAD has found that breathing was a low scoring item [183, 201]. The research conducted by Schuler *et al* [118] demonstrated that consolability scored higher in those without pain than those with pain. Using consolability as an item on the PAINAD tool was also questioned by van Iersel *et al* [201], who suggested that consolability was the result of a treatment, rather than an indication for it. The consolability item did however score reasonably highly with both the pain and false positive groups.

The distribution of the scores was different between the two groups, with those in the false positive group tending not to score on the higher ranked behaviours (the ones scoring two). This is reflected in the different mean and median scores for each group (tables 3.25 and 3.26, p153). These differences were not demonstrated to be significantly different. Therefore, although those without pain may tend to score lower than those with

pain, these differences cannot be used to decide whether someone has pain or the behaviours are due to an alternative cause.

Further analysis was also carried out to examine which DisDAT behaviours were documented when a PAINAD score greater than two was obtained. The ten most frequently occurring behaviours in both the pain and false positive groups are tabulated on p196. This demonstrates that many of the behaviours seen in the two groups were the same, even though the underlying cause was different. There were four behaviours observed frequently in the pain group that were not observed as frequently in the false positive group. All of these behaviours were seen in the false positive group, but to a lesser frequency. The same is true for the frequently observed false positive behaviours that were not seen as frequently in the pain group.

The research has demonstrated that the breathing item on the PAINAD tool scores infrequently, as also demonstrated in previous research utilising PAINAD. Despite the apparent differences in the scoring on PAINAD from the pain and false positive groups, significant differences in overall scores were not demonstrated. As 33% of the study participants scored greater than two on the PAINAD tool, despite not being in pain, this suggests that PAINAD is not specific with regards to identifying pain. There were many behaviours, generated by using DisDAT, that were seen in both the pain and false positive groups observations. This therefore calls into question the ability of any behavioural assessment tool to differentiate pain from other causes of distress.



## **4.11 Discussion of medication results**

### **4.11.1 Analgesia results**

The analgesic prescriptions of all participants were documented at the start of the research. The analgesics were divided depending on how they were prescribed. Those who were prescribed analgesia both regularly and “as required” were put into the regular analgesia group. In the current study 14% of participants were prescribed analgesia regularly, 33% solely on an “as required” basis and 53% were not prescribed any analgesia. There are few studies that look specifically at general analgesic prescribing in nursing homes, with most examining prescribing practices for those with pain [104] or the analgesics that were prescribed [256, 257] rather than how the analgesics are prescribed. A recent study carried out by Smalbrugge *et al* [258] of 290 Dutch nursing home residents demonstrated that 45.9% were prescribed regular analgesia, 8.6% “as required” analgesia and 45.5% were not prescribed any analgesia. It is possible that these differences between the current research and the Smalbrugge study may be caused by differences between nursing homes in Holland and the UK. One such difference is that Dutch nursing homes often have specifically trained nursing home physicians, which may lead to the differences seen.

#### **4.11.1.1 Analgesic drugs prescribed**

Paracetamol was the most commonly prescribed drug, both as a regular prescription and on an “as required” basis. This is in keeping with the study by Allcock *et al* [109] carried out in nursing homes in Nottingham, which demonstrated that paracetamol was the most

“often” used analgesia for pain. Paracetamol was also the most frequently prescribed analgesic in nursing homes in the studies conducted by Smalbrugge and Won [104, 258]. The frequent prescription of paracetamol for pain is probably accounted for by a) it is the first step of the WHO analgesic ladder, b) its lack of gastrointestinal side effects and c) the small incidence of drug interactions [125]. It is, therefore, regarded as a relatively safe drug to be used in this population.

Weak opioids were the next most frequently prescribed analgesic, sometimes prescribed in combination with paracetamol. None of the participants in the current research was prescribed strong opioids. The finding for weak opioid prescription are similar to those found in the study by Allcock *et al* [109], however 19% of nursing home residents in their study were “often” prescribed strong opioids for non-malignant pain. In the study by Won *et al* [104] examining prescribing patterns in nursing homes, 3% of the residents who had pain were prescribed strong opioids. It is possible that, as the comparable studies of analgesic prescribing in nursing homes involved larger numbers of participants, the number of participants in the current research was too small to identify participants requiring strong opioids. Another possibility is that strong opioids were prescribed less owing to concerns regarding side effects, such as confusion. Several authors have demonstrated that opioids are prescribed less frequently to those with more severe cognitive impairment [120, 121, 259, 260] and have cited fears regarding worsening confusion as a potential reason for this phenomenon. Research by Allen *et al* [261] examining nursing home residents’ activity in relation to analgesia prescribed, after controlling for functional ability, demonstrated that those prescribed opioid analgesics

spent less time being inactive than those not prescribed analgesic medication. The authors suggest that this may have been due to the opioids controlling pain better, allowing greater activity and not causing sedation. Despite all these potential reasons, a possible cause for strong opioids not being prescribed could have been that these drugs were not required to control their pain. None of the participants was prescribed strong opioids following the assessments for pain.

Only two participants were prescribed NSAIDs, with one prescribed oral diclofenac and the other prescribed ibuprofen gel. This is a smaller proportion than in the studies by Smalbrugge (20%) and Allcock (46% “often” prescribed NSAIDs) [109, 258]. The American Geriatrics Society has suggested that NSAIDs should be avoided in those needing long term daily analgesic therapy in view of gastrointestinal side effects [123]. It is possible that local prescribing practices reflect these concerns.

Only one participant was prescribed an adjunct analgesic (Baclofen) in the current research. In the study by Allcock [109], antidepressants and anticonvulsants were prescribed “often” for 4% of nursing home residents; most other comparative studies do not have data for adjuvant analgesics. It would seem, therefore, in both the current study and other research carried out in nursing homes, that adjuvant analgesics are infrequently prescribed. If identifying pain in those with severe dementia is difficult, then understanding the nature of the pain may be more challenging. The lack of prescription of adjuvant analgesia, particularly for neuropathic pain, may be due to the difficulties in recognising neuropathic pain in those with cognitive impairment. Neuropathic pain has

several characteristics: there is often an area of abnormal sensation associated with the pain, there is often a hyperpathic state characterised by allodynia, summation and radiation of the pain and neuropathic pain is often described in a specific way (as burning, shooting etc.) [262]. Eliciting the history and physical signs of neuropathic pain will be more challenging in patients with severe cognitive impairment who may be unable to describe their pain or respond to questions regarding sensation. Hence recognising that pain has a neuropathic origin may be more challenging and the appropriate prescription of medication for neuropathic pain may occur less frequently.

The level of non-pharmacological strategies for pain management, employed prior to the current study, was not formally assessed. If a participant was found to be in pain, then the non-pharmacological strategies that had already been tried were discussed with nursing home staff.

In summary, paracetamol was the most commonly prescribed analgesic in the current research, in keeping with other research examining the prescribing practices in nursing homes. Weak opioids and NSAIDs were prescribed less frequently, with no participants prescribed strong opioids. This may reflect the fears regarding prescribing opioids for those with severe dementia or may also be simply due to the number of study participants and the severity of their pain. Few adjuvant analgesics were prescribed, potentially due to the difficulties in assessing the nature of pain in those with severe cognitive impairment.

#### **4.11.1.2 Association of analgesia with groups following initial assessment**

Analysis using Fisher's exact test of the data regarding analgesic prescription and groups following the initial assessment revealed a significant association ( $p = 0.011$ ). As discussed previously, the numbers for some of the groups were too small for further analysis. There are, however, several interesting points for discussion from examination of table 3.11 on p141. From those who were found to have pain, six were already prescribed regular analgesia. Several studies examining the prevalence of under-treated pain in the elderly have used prescription of analgesia to indicate that pain is adequately treated [2, 104, 257, 261, 263]. The finding that 46% of those with pain were already prescribed regular analgesia suggests that using analgesia as a marker for adequate pain management is misleading. In addition, a recent review of pain management stated that "pain per se should be assessed, rather than surrogate measures such as analgesia use" [230]. These findings have important implications for designing future research regarding pain prevalence.

#### **4.11.1.3 Association with homes used in the study**

Analysis using the Fisher's exact test demonstrated a significant association between the homes involved in the research and how analgesia was prescribed ( $p < 0.001$ ). This was further investigated by comparing the three EMI homes with each other. No significant differences were found in analgesic prescribing practices. The analgesic prescribing practices of the NHS ESMI home was then compared to the non NHS EMI homes. Further analysis using Fisher's exact test demonstrated a significant association between type of home and how analgesia was prescribed. By examining table 3.57 on p202, there

are obvious differences between prescribing practices. In the ESMI home only one person did not have analgesia prescribed and 69% participants had as required analgesia prescribed, mostly paracetamol. It is possible that this was a policy decision at the ESMI home; however there was no association demonstrated between those who had pain and the place of residence. Therefore having most residents prescribed some form of analgesia did not lower levels of identified pain.

It is possible that having analgesia “as needed” for unpredictable pain may be of benefit so that pain relief can be given by nursing staff without needing to wait for medical staff review. This does, however, rely on the nursing staff being able to recognise when the person is in pain. Work carried out by Nygaard and Jarland in Norwegian nursing homes demonstrated that those with dementia were less likely to receive PRN analgesia than those who were cognitively intact [264]. Even if pain is successfully identified it can be challenging to give suitable analgesia. Once the person has pain they are often distressed, making it more difficult to administer oral medication. Therefore if pain is frequently occurring, prescribing regular analgesia is more successful. This was recognised whilst carrying out the current research and reflected in the analgesia prescribed for those with pain, with most participants being prescribed regular analgesia. (Table 3.35, p160)

To summarise, statistically significant associations were demonstrated between the analgesia prescribed and the groups following the first assessment and also the type of home. Using prescription of analgesia as an indication of adequate pain control may be misleading, as demonstrated by six of those with pain already being prescribed analgesia.

Over two-thirds of the participants from the NHS home were prescribed PRN analgesia; however this may simply reflect prescribing policy. If pain is occurring frequently, giving analgesia regularly may be more successful than relying on PRN analgesia.

#### **4.11.2 Central nervous system drugs**

A statistically significant association was not demonstrated between the prescription of any of the drugs with central nervous system actions and the groups following the first assessment. Particularly of note is the lack of an association between the false positive group and antipsychotic drug prescription. This group has been demonstrated to have significantly higher CMAI scores than the other groups. A high proportion of nursing home residents with dementia are treated with antipsychotic medication for behavioural symptoms [265]. The lack of an association may be due to the application of good practice guidelines that recommend utilising psychological or environmental options as a first line approach [266].

#### **4.12 Discussion of inter-rater reliability**

To obtain a measure of inter-rater reliability, a proportion of observations were repeated by a second researcher. Initially it was envisaged that this would occur at the same time as the main researcher. Owing to the work schedules of both the main and second researcher this was impossible to carry out and therefore the repeat observations were carried out within a week of the observations conducted by the primary researcher. This factor is likely to have strongly influenced the results as specific circumstances, that may affect behaviour, can vary from day to day. In addition, the number of dual observations is small, particularly for the intervention observations. These factors may explain to a certain extent why the agreement between most of the observations was poor or worse than would have been expected by chance.

If both researchers had carried out the observations at the same time, it is possible that this may have influenced the behaviour seen. As discussed previously, the presence of a researcher in the room whilst care was being given could potentially be distressing to the participant. It was felt that this issue did not occur to a great extent during the research. The presence of two unknown people, however, could have been more distressing and may have led to several observations having to be abandoned.

Other potential influencing factors are connected with the tools themselves. The behaviours on the DisDAT were initially recorded by the main researcher from the background knowledge of the nursing staff and would therefore be more easily understood by the main researcher. It is possible that the behaviours described may not



have been interpreted in the same way by the second researcher. In addition, the lack of a time frame in the PAINAD tool for the length of time a behaviour is observed may have affected the results. For example, if a participant had smiled and then briefly grimaced during an observation, the facial expressions observed may have been scored differently by the two researchers.

It is worth noting that the inter-rater reliability of PAINAD has been addressed in several previous studies, describing it as good [3, 183] or fair [196]. The inter-rater reliability of DisDAT has not been established yet, although there are ongoing research studies aiming to address this.

In summary, as the inter-rater reliability was not carried out at the same time, a true measure of this aspect of the tools' utility was not accurately established. Carrying out true inter-rater reliability would pose some difficulties, especially for some participants where distress might be caused by having two researchers present. Despite the lack of agreement between most observations, interesting issues have been raised. For instance, when using DisDAT, it is important to ensure that behaviours listed are readily understandable by all; in addition, the research has also demonstrated the variability of behaviour in those with severe dementia. This variability may make it necessary for assessment tools to be repeated to obtain a true picture of a person's behaviour. In view of the difficulties highlighted by this study regarding the establishment of the inter-rater reliability of both tools, further firm conclusions about this aspect of validity require further research.

#### **4.13 The assessment and management of pain in dementia**

From reviewing the literature on pain in those with severe dementia, there are few studies that address the prevalence of pain in this group. Some research studies have involved those with moderate levels of dementia [116-118], but many studies examining pain in dementia excluded participants with more advanced dementia because of communication difficulties. The current research found that 16% of the study participants were in pain during at least one of the baseline assessments. This is less than the figures of 32-62% that were given as the percentages of those in pain in studies of people with moderate dementia [116, 117]. I have conjectured that this might be caused by the combination of a short observation period, the effects of dementia on pain pathways and the behavioural tools assessing a different aspect of pain experience from self-assessment tools, which were used in one of the earlier studies [116]. How much these factors have potentially affected the true prevalence of pain in severe dementia is difficult to quantify. It does remain important, however, that pain is adequately identified and managed. Many of the participants who were found to be in pain had not had their pain identified and clearly benefited from this being alleviated. As there were no specific associations with pain and variables such as dementia diagnosis, age or sex, it is not possible to target one group specifically in terms of assessing for pain.

##### **4.13.1 The use of pain assessment tools**

The American Geriatrics Society, in their guidelines regarding the management of persistent pain in older persons, suggest that pain should be assessed in those with moderate to severe dementia via direct observation or history from care givers [123].

They recommend observing for evidence of pain-related behaviours and unusual behaviour that might trigger assessment for pain. Pain assessment tools may have a variety of purposes; to identify the presence of pain, determine the severity of pain and assess the effectiveness of interventions to treat pain [170]. The current research has questioned the ability of PAINAD solely to identify pain. Although most of the participants who were felt to be in pain had PAINAD scores of greater than two, 33% of the study participants also had PAINAD scores of greater than two who were not felt to be in pain. It would appear, therefore, that PAINAD will identify behaviours that may indicate pain, but further analysis of the observed behaviours is still then required. This was highlighted in the review of pain tools carried out by Keela Herr who commented that “the identification of pain indicators using a standardised tool is only one step in a complex diagnostic process” [31]. It is difficult to extrapolate this finding to all behavioural pain assessment tools, but it has been argued that there is no evidence that there are any behaviours that solely indicate pain [4]. It becomes likely, therefore, that other assessment tools, consisting of a list of pain behaviours, may also identify behaviour that is not caused by pain. This was a finding of a recently published paper, demonstrating that Doloplus-2 may also identify discomfort from causes other than somatic pain [192].

A recent consensus statement regarding pain assessment, in those unable to communicate, highlighted that most pain assessment tools cannot be considered to represent definitive indicators of pain [170]. The recent NICE-SCIE guideline [20], however, states that health and social care professionals should use an observational pain assessment tool, if

helpful, when assessing whether a person with dementia is in pain. It is highlighted that the possibility of other causes for unexplained changes in behaviour should be considered.

When behaviour pain assessment tools do identify pain, can they assess severity of the pain? This question was not specifically addressed by the current research. However the research by Schuler *et al* [118] compared the scores from using the PAINAD with a VAS of intensity of the assumed pain completed by the nursing staff. They found no relationship between intensity of assumed pain and the magnitude of pain behaviour displayed, concluding that PAINAD does not provide a graded pain severity scale. The lack of a relationship may simply reflect the difficulty caused by a surrogate trying to assess how severe the pain is, however, there are other reasons why assessing severity using observed behaviour is problematic. A patient needs to be able to display all of the behaviours contained within the scale for that scale to be suitable for use [182]. If a patient is immobile and completely dysphasic, they will be unable to produce a high score on most scales, no matter how severe the pain is. In addition, individual variability in observed behaviour exists not only on account of the existence of pain, but also on account of its severity. This makes creating a tool that can adequately capture this variability extremely challenging [31]. There has not been any research published that shows a correlation between pain intensity and either a specific behaviour or number of behaviours in any population [182].

The current research did demonstrate, however, that behavioural pain assessment tools can assess the effectiveness of interventions to treat pain. The PAINAD score for those with pain was significantly less following intervention for pain. Several authors have also highlighted that behavioural pain tools can be used for this purpose [31, 182]. It would therefore seem that behavioural pain assessment tools will identify pain (as well as behaviour owing to other causes), but can be used successfully to indicate the efficacy of interventions for pain. They are, however, unreliable indicators of pain severity.

#### **4.13.2 The use of behavioural distress assessment tools**

The current research also utilised a distress assessment tool, DisDAT. This tool differed from PAINAD in several respects. The main differences were that it sought to identify distress rather than pain and the behaviours that formed the tool were behaviours that the participant had been recognised to display. The principle of identifying distress first and then evaluating the cause, would prevent the incorrect labelling of behaviour as caused by pain that can occur if pain tools are used at face value. Many of the published pain tools have identified that this can be an issue [3, 185, 187, 192], yet do not provide advice on how to decide what the cause of the behaviour is. The current research has demonstrated that by using a pain assessment tool, a third of those participating had significant scores but had distress from causes other than pain. Alleviating this distress is clearly important. A recent report highlighted that those with advanced dementia often have unresolved symptoms of distress contributing to suboptimal terminal care [19]. Identifying and attempting to manage distress, whatever the cause, would seem an essential goal in good quality care for those with severe dementia.

Using the DisDAT to create lists of distress behaviours highlighted the huge variation seen in behaviours that the study participants might display. Concerns have been raised by several authors that using a limited number of behaviours to assess pain runs the risk of ignoring unique behaviours that might indicate pain [31, 170]. Therefore, by creating a list specifically relating to the person, these unique behaviours are captured. This approach does presume that those caring for the person recognise and correctly interpret all the person's behaviours of distress. On a few occasions, whilst the DisDAT was being completed, staff would remark that they were unsure of the true significance of certain behaviours, whether they were habitual or indicative of distress. This can be an issue with any list of behaviours that are used as a tool for assessing pain or distress. A further issue is ensuring that the behaviours documented are understandable to all that will be using the tool. The DisDAT was not designed to be a scoring tool, but monitoring sheets can be used to monitor a therapeutic intervention. The current research has demonstrated that the DisDAT can be used to assess the effectiveness of interventions by using such monitoring sheets (Appendix p331).

#### **4.13.3 Using behavioural assessment tools as part of good quality care**

Published research suggests that around 25% of nursing homes use a standardised pain assessment tool [109]. The current research findings have suggested that using a behavioural distress tool may be a more appropriate method to identify behaviour and monitor the effectiveness of interventions. The current research has also given indications of how such tools should be used. The underlying causes for observed pain could be divided into three broad groups: acute pain events, worsening of known chronic

diagnoses and new, slower onset painful conditions. The acute events had often been identified by the staff, whereas worsening of chronic conditions or new slow onset problems had not been identified. In order to ensure that the pain is identified in all cases, regular use of behavioural assessment tools in all of those with severe dementia is required. In addition, simply performing an assessment is meaningless unless an evaluation of the behaviour seen takes place and appropriate action taken to alleviate the underlying cause. This may require input of not only the nursing staff but other members of a multidisciplinary team. The frequency with which the assessments take place is important in order to avoid burdening carers, but they should not be so infrequent that pain is missed. One potential solution is to perform an assessment, prior to a formal review of a person with dementia, so that this information can be reviewed by all of those involved in their care. Carrying out assessments in this way will depend on how frequently such reviews take place. The current research did not reassess those found not to be in pain or distress from other causes, following the baseline assessment. It is not possible from the current work therefore to provide a timeframe for regular pain review; this is an area for potential future research.

A more frequent review of pain will need to be undertaken in those recognised to be in pain, and who have had changes made to their treatment. In the current research a significant difference was not seen between the one month and three month scores. There were, however, some participants whose pain worsened in this two month time frame (see vignette 1b). A sensible approach may be to review on a regular basis once a change to management has been implemented and then plan regular reviews of their pain depending

on the natural history of the underlying condition. As highlighted previously in the discussion, complete resolution of all behaviours seen may not be a suitable goal of pain treatment [180].

The amount of time that should be observed in order to complete a behaviour assessment is an interesting question. Some tools, such as PAINAD, describe the observation being carried out for a specific period of time (five minutes). This short time frame was used in the current research, although concerns could be raised that only observing for a short time frame may risk ignoring large parts of a person's day where pain may occur and behaviours not be observed. One solution is to broaden the time frame, for example, completing the tools recalling the behaviours seen over the course of a day. This will create a better overall picture, yet it runs the risk of behaviours being either ignored or forgotten. Interpreting the behaviours that are documented will be more challenging as the exact circumstances that either provoked or alleviated the behaviour may be difficult to recall. This way of using behavioural tools has not been explored by the current research and would provide a focus for future research.

#### **4.13.4 The management of pain in dementia**

In managing the pain that was identified during the study, several factors were critical. Identifying the underlying cause was the first step, using medical and GP records as well as examination of the participant. Following a review of previously used therapies, suitable management was planned. This took into account factors such as how able the participant was to take medication, known allergies and other medical conditions such as



renal impairment. If medication was given, it was given regularly and its effectiveness reviewed regularly. These pain management principles are well established [123, 208], however it was important for the research to demonstrate that following such principles, effective management strategies could be found. The current research did demonstrate that non-pharmacological techniques were useful in managing the identified pain; this relied to some extent on the willingness of the nursing home staff to ensure that changes to management were carried out.

Paracetamol was prescribed frequently for pain prior to the study commencing. This drug was also prescribed several times to treat musculoskeletal pain identified during the study. The efficacy of paracetamol in this population was demonstrated in this study. NSAIDs were not frequently used in the current research, other than in topical form for painful joints. This reflects recommendations to avoid regular prescription of oral NSAIDs in this group owing to potential side effects in this population, and also recent research evidence regarding the use of topical NSAIDs [267]. Although strong opioids were not prescribed for any participants in the current research, the participants prescribed weak opioids may require prescription of these drugs should their pain worsens in the future.

To summarise, the current research has demonstrated the need for an individualised approach to managing pain in dementia, utilising a range of pharmacological and non-pharmacological therapies tailored to the underlying cause for the pain. The principles of the WHO analgesic ladder were used successfully to manage pain; however the

continuing review of those identified as being in pain is vitally important to ensure pain management remains adequate.

#### **4.14 Palliative care in dementia**

The current research has highlighted the need for regular assessment of those with advanced dementia, not just with regards to pain, but also to assess distress from a wide range of causes. Such assessments could potentially require input from a wide ranging multidisciplinary team. This might include psychiatrists, palliative care physicians and geriatricians as well as nursing, physiotherapy and speech therapy input. The challenge of improving the quality of care for those with advanced dementia has recently been recognised by several key national and international bodies such as the WHO [10], NICE-SCIE [20] and the Department of Health [268]. How this challenge is met in the UK, particularly in the face of the rising numbers of people with dementia, is an area of debate at both national and local levels [269]. The accessibility of palliative care services for those with advanced dementia is one component in improving quality of care.

As discussed in the introduction, defining the terminal stage of dementia can be problematic, particularly as those with dementia do not necessarily deteriorate in an ordinal manner [98]. There may be palliative care issues occurring throughout the course of the illness, not just in the final few months. The identification of such issues also requires appropriate referral to those most able to deal suitably with them. There may not be a specific point during the illness where the emphasis changes from active to palliative care, rather there will be a balance of approaches depending on the specific situation [95].

In the US, hospice care is the standard method for providing quality end of life care, provided to patients in the last six months of life. Although this type of care is increasing

for those with dementia [270], only around one in ten will be enrolled in hospice care. Research has demonstrated levels of increased satisfaction amongst families whose relatives are cared for in such programmes [271, 272]. Other groups in the US have recommended that those with dementia would benefit from similar care throughout their illness. The Palliative Excellence in Alzheimer Care Efforts (PEACE) programme incorporates advance planning, patient centred care, family support and a palliative care focus from diagnosis to terminal stages [273]. Initial feedback suggests high levels of satisfaction from both patients and carers to this approach. A recent review of the scientific evidence for the efficacy of a palliative care approach in advanced dementia, concluded that there is only equivocal evidence for such an approach [274]. Only two papers were identified by the review that met full criteria for inclusion and both papers originated from the US. The authors acknowledge that carrying out randomised controlled trials of end of life care for these patients is problematic, leading to a lack of such trials.

As palliative and hospice care is structured and financed differently in the UK, it is difficult simply to adopt models of care from other countries, such as the US, and apply them directly. The numbers of patients with dementia admitted to hospices are currently small [10, 15], with only 1-2% of admissions having dementia as the primary diagnosis. The reasons for this are not clear; one possible reason may be the beliefs regarding which patients can be referred to hospices. It is possible, however, that many potentially suitable patients are not referred as there are concerns regarding removing them from their current environment and placing them in another, not suited to those with dementia. If this is the

case, then providing care to the level that might be achieved in a hospice environment should be attempted wherever that person is, whether it is their own home, a hospital or care home.

The range of palliative care issues that may be seen as dementia progresses will vary from person to person. The focus of the current research has been on the assessment and management of pain and has highlighted the importance of recognising distress from a variety of causes. Other important issues may include feeding issues, support for families and end of life care, as discussed in the introduction. Recognising these issues is one aspect; however having the available resources to meet these needs is another. During the course of the research it became apparent that providing non-pharmacological strategies to deal with pain could be more challenging than one might expect for palliative care patients. Accessing the services of physiotherapists, occupational therapists and complementary therapists was not impossible, but much less readily available than might be to those under the care of a hospice.

It has been recognised that general palliative care should be provided by all of those caring for patients with chronic progressive illnesses, with specialist palliative care provided by skilled multi-professional teams [76]. With this principle in mind, adequate training must therefore be delivered to all professionals involved in providing care to those with dementia. Staff shortages within nursing homes may prevent members of staff from attending such training sessions and limit the ability of staff to deal effectively with a variety of palliative issues including the management of pain [204, 260, 275]. There

may also be high staff turnover within homes, reducing the capacity to maintain a core of highly trained staff with in depth knowledge of the people they care for. These barriers were highlighted by work carried out by Hockley *et al* in promoting the Liverpool care pathway for the dying in nursing homes [89]. They also discussed the difficulties encountered in dealing with the many different GPs connected with one home in terms of coordinating services. Two out of the three EMI homes in the current research had most of their residents' care transferred to one GP, who provided weekly visits. Inadequate physician presence in nursing homes has been highlighted in other work as a barrier to the delivery of high quality care [260, 275].

The provision of education and training should not only include those who provide day to day care for those with dementia, but also for the specialist teams that may also be involved in their care. Few community palliative care clinical nurse specialists hold a specialist qualification in the care of older people [22] and many dementia care specialists lack confidence in providing palliative care [63]. A collaborative approach between the different groups involved in providing care, sharing knowledge and expertise has been suggested as a method of enhancing care [276]. Developing links therefore between psychiatry of old age, palliative care and geriatric medicine is critical in providing coordinated care for those with dementia [63].

## **Chapter 5 ~ CONCLUSIONS**

### **5.1 Summary of thesis aims**

This thesis reported the results of a pilot study assessing good practice in pain management in severe dementia. The purpose of the study was to investigate the utility of a pain assessment tool and a distress assessment tool in a UK population with severe dementia and demonstrate the ability of the tools to measure change in pain following change to management regime. This was carried out by completing the tools following three observations, managing any pain observed and then repeating the tools. In addition, the study assessed the use of analgesia within the nursing homes and also examined the nature of distress that may produce a false positive result on a pain scale. The overall aim was to demonstrate the importance of managing pain as part of good quality palliative care for people with severe dementia.

### **5.2 Summary of outcomes of literature review**

In this section I shall summarise the results of the literature review presented in Chapter 1 and show how the review generated my research hypotheses. The literature review covered a wide range of issues pertaining to palliative care and pain in severe dementia. As dementia is a progressive life threatening condition, it has been recognised that the principles of palliative care should apply to patients with dementia [1, 15, 16]. The palliative needs of dementia patients have been examined retrospectively using interviews and MDS data [34, 35] and the identified needs discussed in more detail. Decision making surrounding physical issues such as feeding and treating infections can

be complex and the need consider advance care planning was highlighted. The specific needs of those with dementia regarding family support, psychological and spiritual issues and end of life care were examined and recent initiatives to address these concerns are discussed. The timing of such input was also debated, with the recognition of the difficulties in identifying the end of life phase of dementia. As many of the discussed issues can occur at any stage in the illness [101], the importance of a balance between palliative and active approaches was emphasised.

### **5.2.1 Pain in dementia**

The literature review of pain in dementia initially considered levels of pain in elderly population to give an indication of potential levels of pain in those with severe dementia. Although pain was found to be common [2, 103] and often under-treated, it was recognised that those with severe dementia were invariably excluded from such studies. Other methods of evaluation the prevalence of pain were therefore reviewed. The studies carried out by Morrison and Feldt [120, 121] demonstrated the differences in opiates given, following hip fracture, to those with cognitive impairment compared to those with normal cognition. This raised the issue that the neuropathological changes of dementia may affect pain pathways and the evidence for and against this phenomenon was discussed. Although there are published case reports [132] and theoretical evidence [130, 131] for altered pain perception in Alzheimer's disease, this has not been demonstrated by recent work utilising fMRI techniques [141]. There is less published evidence regarding vascular dementia and the studies available are far from conclusive. The potential impact of neuropathological changes regarding pain perception is difficult to



quantify as dementia progresses. Therefore defining the true prevalence of pain in severe dementia is complex.

The first research hypothesis to be tested was that pain is common and under-recognised in this population

### **5.2.2 The assessment of pain in dementia**

The literature review also described the use of self assessment pain tools in dementia and highlighted that most scales could not be completed with worsening cognitive ability. The use of behavioural pain assessment tools was debated and several problems with this approach were raised. Recent reviews of such tools [31, 184] have demonstrated that the lack of behaviours solely indicating pain may lead to pain being over identified. In addition, many behavioural pain tools risk ignoring unique indicators of pain. A recent review was unable to recommend one tool for use across population and settings [170]. In view of these issues, two different tools were chosen for use in the study, PAINAD [3] and DisDAT [4]. The published evidence surrounding the utility of PAINAD was discussed, including its ease of use and change in scores seen on treatment of pain [3, 195, 229]. The concerns that have been raised regarding PAINAD identifying behaviour that was not caused by pain [201] were explored, as well as concerns that the tool cannot indicate pain intensity [118]. The principles regarding the use of DisDAT were discussed, including its aim of identifying distress rather than pain and allowing unique behaviours to be utilised in assessment.

Several research hypotheses were created following this review: that behavioural assessment tools can reliably be used to identify pain and the tools are sensitive to changes in pain. In addition, assessing the nature of distress that may produce a false positive result on a pain scale formed another research objective.

### **5.2.3 The management of pain in dementia**

The literature review regarding pain management initially covered some of the issues regarding prescribing drugs for elderly patients, including pharmacodynamic and pharmacokinetic changes that can alter drug actions. The different groups of drugs that form the WHO analgesic ladder were discussed and the principles regarding their use in elderly patients were examined. Adjuvant analgesia and non-pharmacological approaches were also considered, including prevention of painful events. The literature regarding prescribing analgesics to all agitated patients was reviewed and several concerns were raised regarding this approach.

The principles regarding analgesia prescription lead to the final hypotheses being formed. These were that analgesia is prescribed inadequately for those with dementia and that pain identified can be managed using both simple non-pharmacological and pharmacological techniques.

### **5.3 Main findings of the research**

In order to test these hypotheses, I undertook a pilot study of 79 nursing home residents with severe dementia. The participants all had a CDR score of three and were resident in four homes in the North Tyneside area.

#### **5.3.1 Background**

Many of the characteristics of the population included in the research were comparable to national data and other published studies. The proportion of participants with vascular dementia was higher than might have been predicted, with fewer participants diagnosed with Dementia with Lewy bodies. It was not clear whether these differences influenced the results of the research. The wide variation in time since diagnosis and time since admitted to the home meant that the participants were representative of a broad range of patients with dementia. The background neuropsychiatric scales demonstrated that levels of depression were similar to those seen in other dementia research and levels of dependency were in keeping with placement policy for those with advanced dementia. Levels of psychopathology were lower than those seen in other research studies of dementia, with agitation levels slightly higher.

#### **5.3.2 Results from baseline assessments**

Following the baseline assessments, 16% of participants were found to be in pain with 33% of participants scoring above two on the PAINAD tool, owing to behaviour from causes other than pain. From this data the sensitivity of PAINAD was shown to be 92% and specificity 61%. The proportion of participants found to be pain was less than had

been expected from studies carried out in patients with moderate dementia. I therefore questioned the hypothesis that pain is common in patients with severe dementia. The potential reasons for the prevalence of pain in this study were discussed. The low prevalence of pain was felt to be caused by a combination of the amount of time used to observe the participants, the possible effects of dementia on pain pathways, the fact that behavioural assessment quantifies a different aspect of the pain experience to self report and that some of the behaviour could have been misinterpreted. Although PAINAD was found to be highly sensitive with regards to pain, I highlighted that the low specificity suggests that this tool cannot be reliably used to identify pain.

#### **5.3.2.1 Associations with groups from baseline assessment**

Statistically significant associations were not demonstrated between a range of variables and the results following the first assessment. These included participants' sex, dementia diagnosis, time since diagnosis or age. I discussed, therefore, that targeting a specific group of patients with advanced dementia would not identify more pain. There was a statistically significant association demonstrated, however, between the scores on the CMAI and the false positive group. The behaviours that were documented were therefore behaviours associated with agitation.

#### **5.3.2.2 Initial PAINAD scores**

There were differences demonstrated in the magnitude of the PAINAD scores in each of the groups from the baseline assessment. The eating observation scores were significantly greater in the false positive group and I discussed that challenging behaviours are

commonly seen at mealtimes [36]. The intervention observation scores were significantly lower in the no pain group, and I suggested that the PAINAD tool may be able to detect when pain is not present. A significant difference was not demonstrated between the PAINAD scores for the pain and false positive groups for the intervention observation. The ability of the PAINAD tool to differentiate between behaviours caused by pain and those not caused by pain was therefore questioned.

### **5.3.3 Results from pain and false positive groups**

#### **5.3.3.1 Pain group**

The causes of the pain identified in the study were first considered. The majority of the pain identified was chronic in nature, with the acute pain having already been identified by nursing staff. As the pain identified was caused by both new diagnoses and previously documented diagnoses, I discussed that all patients with severe dementia may require regular assessments. This would allow monitoring of known painful conditions and identify the onset of new pathologies. I highlighted the need to recognise the underlying cause of the pain, with identified pain managed by simple pharmacological and non pharmacological techniques. A significant difference was demonstrated in the scores on both tools once treatment had started for the identified pain, confirming the hypothesis that the tools are sensitive to change. I debated the timeframe for repeating the assessments, as although a significant difference between one month and three month scores was not demonstrated, some of the pain group had pain at the three month assessment. The need for an individualised time frame for pain assessments was therefore

suggested. The absence of significant change in the neuropsychiatric scores was potentially caused by repeating the scores too soon after implementing pain management strategy. I discussed other important issues (using vignettes), such as how the tools can aid in deciding if treatment has been effective and the difficulties that may be encountered in determining the cause of the behaviour.

### **5.3.3.2 False positive group**

The behaviour seen in the false positive group had a wide variety of causes, with much of the behaviour initiated by the participant either not understanding the situation or becoming distressed by the environment. A statistically significant difference was demonstrated in the agitation scores when repeated at one month. I discussed that this may reflect the fluctuant nature of BPSD [70] and that the homes had attempted to manage some the causes of the identified behaviour. Significant differences were seen in the scores on both tools at rest, possibly owing to the specific circumstances initiating the behaviour not being present at the repeat assessment. Both the changeable nature of BPSD and management strategies introduced by the home were thought to have contributed to the significant change in the PAINAD score on intervention. I discussed the possibility that all of the participants within this group could have been incorrectly labelled as having pain. The recommendation was therefore made that identifying distress should be the first step in identifying pain.

#### **5.3.4 Behaviours observed and documented**

The research demonstrated the range of behaviours that may be recognised as caused by distress and that many behaviours of distress are unique. A variety of behaviours could be documented for all participants, regardless of factors such as age or length of time in the home. The number of behaviours documented was moderately correlated with agitation and psychopathology scores, suggesting that those with agitation may display a wider variety of behaviours of distress. The pattern of behaviours using the PAINAD tool differed between the pain and false positive groups, but the total scores for each group were not significantly different. In addition, as many of the distress behaviours identified were the same in both the pain and false positive groups, I questioned the ability to differentiate between pain and non-pain distress by identifying certain behaviours.

#### **5.3.5 Medication results**

The current research demonstrated that analgesic prescribing practice in the study homes was largely in keeping with published guidelines on pain management, although no participants were prescribed strong opioids. The finding that 46% of those with pain were already prescribed regular analgesia confirms the hypothesis that analgesics may be prescribed inadequately for those with dementia. I also highlighted additional issues such as the need to prescribe analgesia regularly.

#### **5.3.6 Inter-rater reliability**

Although true inter-rater reliability was not achieved in this study, important issues such as the variability in behaviour seen in severe dementia were highlighted.

## **5.4 Strengths and limitations of the research**

### **5.4.1 Generalisability of the study**

An important strength of this pilot study was that all participants had a diagnosis of severe dementia and thereby were appropriate to have their pain assessed using a behavioural assessment tool. As there were no other exclusion criteria, a broad range of participants were involved, including participants who would often be excluded from other studies. All participants were assessed using the tools, therefore using PAINAD and DisDAT as they would be used in day to day practice. Both NHS and non-NHS homes were used in the study, broadening the applicability of the research findings.

There are some factors that limit the generalisability of the research. All the participants in the study were Caucasian and, with only one exception, all British. It is therefore difficult to generalise the study findings to different racial or cultural groups. The proportion of participants with vascular dementia was greater than might have been expected and those with dementia with Lewy bodies less than might have been predicted. The under representation of those with dementia with Lewy bodies may affect the applicability of the research findings to this group. Although many people with advanced dementia live in nursing homes, a proportion live in their own home. The research did not include any participants other than those living in the nursing homes involved in the study. In addition, all the homes included in the study had large numbers of residents with dementia. The findings may not be as applicable to nursing homes with only a few residents with advanced dementia.



#### **5.4.2 Research design**

The assessments were carried out by both the researcher and nursing staff from the home, demonstrating that the tools could be completed by nursing staff as part of routine practice. The participants were observed on three different occasions to give a broader picture of the behaviours that may be identified in different situations. The length of time for each of the observations has been discussed in some detail and difficulties could have been encountered with observing for longer periods of time. It is acknowledged, however, that many potentially important behaviours were not identified by the timeframe given to the observations.

There is no gold standard for identifying pain in those unable to communicate their needs. Any study attempting to investigate this important issue can be criticised for potentially misinterpreting behaviours that could be caused by pain. The underlying cause of all the behaviours that were observed during the research was discussed with the nursing staff present and provoking and alleviating factors identified. If the cause was thought to be pain then the participant was examined where appropriate and previous medical notes reviewed. Despite these measures, it is still possible that some behaviours were not identified correctly.

Finally, the number of participants identified as having pain was relatively small. The prevalence of pain in those with moderate dementia has been demonstrated to be between 32-62%; therefore far more participants were expected to have pain than were eventually identified. Producing definitive conclusions from a small sample of participants (13) is

difficult and this limited the statistical analyses that could be completed. In spite of the small numbers identified as having pain, it was possible to demonstrate that the tools were sensitive to change and recognise important patterns in those identified as having pain.

## 5.5 Future research

This study was conducted as a pilot study; therefore the findings of this research should encourage further study. One of the main recommendations of the current research is that all patients with advanced dementia need to be regularly assessed to identify if they are having periods of time of significant distress, and the cause of the distress needs to be addressed. Defining whether this practice is feasible and of benefit to patients could be carried out using a combination of quantitative methods (by demonstrating a change in scores) and qualitative (the nursing staff's opinions of the how beneficial the practice was).

Additional research would help to clarify the most appropriate tools to be used to assess pain and distress in this population of patients. The PAINAD tool, based on a well-validated scale, was known to be easy to use and had previously been demonstrated to have high levels of inter-rater reliability and moderate internal consistency. The initial work by Warden [3] identified that PAINAD scores changed following analgesic administration; this finding was also demonstrated by the current study. The concerns that PAINAD may not solely identify pain were confirmed by the current research, although the tool was demonstrated to have a sensitivity of 92%. By examining the scores obtained from the observations, it was clear that some items on the scale were rarely used, an issue raised by the original research. Although the items on the scale could be modified, this would still not resolve the problem that behaviours that solely indicate pain have not been identified. Any tool that has a list of behaviours that indicate pain may also identify distress that is not caused by pain. The current research, therefore, has questioned the

ability of the PAINAD tool to differentiate between pain and distress from causes other than pain. It has also been suggested that there may be similar problems with other behavioural pain assessment tools. It has been suggested that the Pain Assessment Checklist for Seniors with Limited Ability to Communicate [189] is able to differentiate between pain and non-painful distress states [250], although prospective research has not been published in English to substantiate this claim. Further research using PAINAD and other pain assessment tools with larger numbers of participants would help to clarify whether these tools can differentiate between pain and non-painful distress states. This could be carried out using similar methods to the ones described in the current research.

The current research identified that the DisDAT, initially designed for use in those with learning disabilities, could be used with elderly patients with severe dementia. At least one behaviour associated with distress was identified during pain observations, suggesting that the tool can be used to identify distress caused by pain. In addition, by using a PACA scoring system, a significant change was seen in the scores on treating pain. As the number of participants in the pain group was small, further research using larger numbers of participants would help to ascertain whether these findings could be replicated. It is difficult to demonstrate many psychometric properties of the DisDAT as the tool is created specifically for the individual by documenting their behaviours of distress and is not designed to be a scoring tool. However some aspects of the tool, such as inter-rater reliability could be established by further research and this would help to determine the utility of the tool for day-to-day usage.

Further work is required to help to define the optimum time used for observation. Although it may be helpful to have a flexible approach, understanding the differences between observing behaviour for a short period of time as compared with a longer time frame may help in selecting an appropriate length of time for observation in this group of patients. Although some attempt was made in the current research to quantify how frequently such assessments should occur, this could be more effectively addressed in a larger study. With a larger cohort of participants, a better assessment could also be made of whether changes might be seen in neuropsychiatric parameters on treating pain.

Finally the aim of this research was to demonstrate the importance of managing pain as part of good quality palliative care in people with severe dementia. Several reviews have suggested that much needs to be done to improve the quality of care for people with dementia [63] and questions remain about how best to provide this care [33]. The need for continuing debate and research regarding the provision of palliative care for dementia patients remains of high importance if the WHO goal of providing palliative care to all those with life-threatening illness is to be achieved.

## **Chapter 6 ~ APPENDIX**

Clinical Dementia Rating scale

Clifton Assessment Procedure for the Elderly - Behaviour Assessment Scale

Cohen Mansfield Agitation Inventory

Cornell Scale for Depression in Dementia

Neuropsychiatric Inventory

Pain Assessment in Advanced Dementia tool

Disability Distress Assessment Tool (with monitoring sheet)

Oral presentations

Poster presentations

Publications

**Clinical Dementia Rating scale (CDR) [134, 135]**

	<b>None 0</b>	<b>Questionable 0.5</b>	<b>Mild 1</b>	<b>Moderate 2</b>	<b>Severe 3</b>
<b>Memory</b>	No memory loss or slight inconsistent forgetfulness	Consistent slight forgetfulness; partial recollection of events; "benign" forgetfulness	Moderate memory loss; more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
<b>Orientation</b>	Fully oriented	Fully oriented except for slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented to time, often to place	Oriented to person only
<b>Judgement and problem solving</b>	Solves everyday problems & handles business & financial affairs well; judgment good in relation to past performance	Slight impairment in solving problems, similarities, and differences	Moderate difficulty in handling problems, similarities, and differences; social judgment usually maintained	Severely impaired in handling problems, similarities, and differences; social judgment usually impaired	Unable to make judgments or solve problems
<b>Community Affairs</b>	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activities	Unable to function independently at these activities although may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside home Appears well enough to be taken to functions outside a family home	No pretense of independent function outside home Appears too ill to be taken to functions outside a family home
<b>Home and Hobbies</b>	Life at home, hobbies, and intellectual interests well maintained	Life at home, hobbies, and intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in home
<b>Personal care</b>	Fully capable of self-care	Fully capable of self-care	Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence

Score only as decline from previous usual level due to cognitive loss, not impairment due to other factors.

### **Assignment of CDR rating**

Use all information available and make the best judgment. Score each category (M, O, JPS, CA, HH, PC) as independently as possible. Mark in only one box, for each category, rating impairment as decline from the person's usual level due to cognitive loss alone, not impairment due to other factors, such as physical handicap or depression. Occasionally the evidence is ambiguous and the clinician's best judgment is that a category could be rated in either one of two adjacent boxes, such as mild (1) or moderate (2) impairment. In that situation the standard procedure is to check the box of greater impairment.

Aphasia is taken into account by assessing both language and non-language function in each cognitive category. If aphasia is present to a greater degree than the general dementia, the subject is rated according to the general dementia. Supply evidence of non-language cognitive function.

The global CDR is derived from the scores in each of the six categories ("box scores") as follows.

Memory (M) is considered the primary category and all others are secondary. CDR = M if at least three secondary categories are given the same score as memory. Whenever three or more secondary categories are given a score greater or less than the memory score, CDR = score of majority of secondary categories on whichever side of M has the greater number of secondary categories.



When three secondary categories are scored on one side of M and two secondary categories are scored on the other side of M, CDR=M.

When M = 0.5, CDR = 1 if at least three of the other categories are scored one or greater.

If M = 0.5, CDR cannot be 0; it can only be 0.5 or 1. If M = 0, CDR = 0 unless there is impairment (0.5 or greater) in two or more secondary categories, in which case CDR = 0.5.

Although applicable to most Alzheimer's disease situations, these rules do not cover all possible scoring combinations. Unusual circumstances occur occasionally in Alzheimer's disease and may be expected in non-Alzheimer dementia as well are scored as follows:

(1) With ties in the secondary categories on one side of M, choose the tied scores closest to M for CDR (e.g., M and another secondary category = 3, two secondary categories = 2, and two secondary categories = 1; CDR = 2).

(2) When only one or two secondary categories are given the same score as M, CDR = M as long as no more than two secondary categories are on either side of M.

(3) When M = 1 or greater, CDR cannot be 0; in this circumstance, CDR = 0.5 when the majority of secondary categories are 0.

## Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale [227]

1. When bathing or dressing, he/she requires:
 

No assistance	0
Some assistance	1
Maximum assistance	2
  
2. With regard to walking, he/she:
 

Shows no signs of weakness	0
Walks slowly without aid, or uses a stick	1
Is unable to walk, or if able to walk, needs frame, crutches or someone by his/her side	2
  
3. He/She is incontinent of urine and/or faeces (day or night):
 

Never	0
Sometimes (once or twice per week)	1
Frequently (3 times a week or more)	2
  
4. He/She is in bed during the day (does not include couch, settee etc):
 

Never	0
Sometimes	1
Almost always	2
  
5. He/She is confused (unable to find way around, loses possessions etc):
 

Almost never confused	0
Sometimes confused	1
Almost always confused	2
  
6. When left to his/her own devices, his/her appearance is:
 

Almost never disorderly	0
Sometimes disorderly	1
Almost always disorderly	2
  
7. If allowed outside, he/she would:
 

Never need supervision	0
Sometimes need supervision	1
Always need supervision	2
  
8. He/She helps out in the home/ward:
 

Often helps out	0
Sometimes helps out	1
Never helps out	2
  
9. He/She keeps him/herself occupied in a constructive or useful activity (works, reads, plays games, has hobbies etc)
 

Almost always occupied	0
Sometimes occupied	1
Almost never occupied	2

10. He/She socialises with others:
- |  |   |
|--|---|
| Does establish a good relationship with others                 | 0 |
| Has some difficulty establishing relationships                 | 1 |
| Has a great deal of difficulty establishing good relationships | 2 |
11. He/She is willing to do things suggested or asked of him/her:
- |                         |   |
|-------------------------|---|
| Often goes along        | 0 |
| Sometimes goes along    | 1 |
| Almost never goes along | 2 |
12. He/She understands what you communicate to him/her (writing, speaking, gesturing):
- |  |   |
|--|---|
| Understands almost everything you communicate      | 0 |
| Understands some of what you communicate           | 1 |
| Understands almost nothing of what you communicate | 2 |
13. He/She communicates in any manner (writing, speaking, gesturing):
- |   |   |
|---|---|
| Well enough to be understood at all times             | 0 |
| Can be understood sometimes or with some difficulty   | 1 |
| Can rarely or never be understood for whatever reason | 2 |
14. He/She is objectionable to others during the day (Loud or constant talking, pilfering, soiling furniture, interfering with the affairs of others):
- |                 |   |
|-----------------|---|
| Rarely or never | 0 |
| Sometimes       | 1 |
| Frequently      | 2 |
15. He/She is objectionable to others during the night (Loud or constant talking, pilfering, soiling furniture, interfering with the affairs of others, wandering about):
- |                 |   |
|-----------------|---|
| Rarely or never | 0 |
| Sometimes       | 1 |
| Frequently      | 2 |
16. He/She accuses others of doing him/her bodily harm or stealing his/her personal possessions:
- |            |   |
|------------|---|
| Never      | 0 |
| Sometimes  | 1 |
| Frequently | 2 |
17. He/She hoards apparently meaningless items (wads of paper, string, food etc):
- |            |   |
|------------|---|
| Never      | 0 |
| Sometimes  | 1 |
| Frequently | 2 |
18. His/Her sleep pattern at night is:
- |                    |   |
|--------------------|---|
| Almost never awake | 0 |
| Sometimes awake    | 1 |
| Often awake        | 2 |

## **Cohen-Mansfield Agitation Inventory [148]**

Behaviour as manifest during the last fortnight

1. Pace, aimless wandering
2. Inappropriate dress or disrobing
3. Spitting (include at mealtimes)
4. Cursing or verbal aggression
5. Constant unwarranted request for attention or help
6. Repetitive sentence or questions
7. Hitting (including self)
8. Kicking
9. Grabbing onto people
10. Pushing
11. Throwing things
12. Strange noises (weird laughter or crying)
13. Screaming
14. Biting
15. Scratching
16. Trying to get to a different place (e.g. out of the room, building)
17. Intentional falling
18. Complaining
19. Negativism
20. Eating/drinking inappropriate substances
21. Hurt to self or others (cigarette, hot water)
22. Handling things inappropriately
23. Hiding things
24. Hoarding things
25. Tearing things or destroying property
26. Performing repetitive mannerisms
27. Making verbal sexual advances
28. Making physical sexual advances
29. General restlessness

Rating:

- 1 = Never
- 2 = < 1 x week
- 3 = 1-2 x week
- 4 = Several times a week
- 5 = Once or twice per day
- 6 = Several times per day
- 7 = Several times an hour

## Cornell Scale for Depression in Dementia [226]

### Scoring System

A = unable to evaluate      0 = absent      1 = mild or intermittent      2 = severe

Ratings should be based on symptoms and signs occurring during the week prior to interview. No score should be given in symptoms result from physical disability or illness.

#### A. Mood-Related Signs

1. Anxiety: anxious expression, ruminations, worrying	a	0	1	2
2. Sadness: sad expression, sad voice, tearfulness	a	0	1	2
3. Lack of reactivity to pleasant events	a	0	1	2
4. Irritability: easily annoyed, short-tempered	a	0	1	2

#### B. Behavioural Disturbance

5. Agitation: restlessness, hand wringing, hair pulling	a	0	1	2
6. Retardation: slow movement, slow speech, slow reactions	a	0	1	2
7. Multiple physical complaints (score 0 if GI symptoms only)	a	0	1	2
8. Loss of interest: less involved in usual activities (score only if change occurred acutely, i.e. in less than 1 month)	a	0	1	2

#### C. Physical Signs

9. Appetite loss: eating less than usual	a	0	1	2
10. Weight loss (score 2 if greater than 5 lb. in 1 month)	a	0	1	2
11. Lack of energy: fatigues easily, unable to sustain activities (score only if change occurred acutely, i.e., in less than 1 month)	a	0	1	2

#### D. Cyclic Functions

12. Diurnal variation of mood: symptoms worse in the morning	a	0	1	2
13. Difficulty falling asleep: later than usual for this individual	a	0	1	2
14. Multiple awakenings during sleep	a	0	1	2
15. Early morning awakening: earlier than usual (for the individual)	a	0	1	2

#### E. Ideational Disturbance

16. Suicide: feels life is not worth living, has suicidal wishes, or makes suicide attempt	a	0	1	2
17. Poor self esteem: self-blame, self-depreciation, feelings of failure	a	0	1	2
18. Pessimism: anticipation of the worst	a	0	1	2
19. Mood congruent delusions: delusions of poverty, illness, or loss	a	0	1	2

## Neuropsychiatric Inventory Questionnaire [228]

Answer the following questions based on changes that have occurred since the patient first began to experience memory problems.

Circle "yes" only if the symptom has been present in the past month. Otherwise circle "no"

For each item marked "yes":

Rate the frequency of the symptom

1 = Occasionally - less than once per week

2 = Often - about once per week

3 = Frequently - several times per week, but less than every day

4 = Very Frequently - daily or essentially continuously present

Rate the severity of the symptom

1 = Mild - produce little distress in the patient

2 = Moderate - more disturbing to the patient but can be redirected by the care giver

3 = Severe - very disturbing to the patient and difficult to redirect

### Delusions

Does the patient believe that others are stealing from him/her, or planning to harm him or her in some way?

Yes                  No

Frequency:

Severity:

### Hallucinations

Does the patient act if he/she hears voices? Does he/she talk to people who are not there?

Yes                  No

Frequency:

Severity:

### Agitation or aggression

Is the patient stubborn and resistive to help from others?

Yes                  No

Frequency:

Severity:

### Depression or dysphoria

Does the patient act if he/she is sad or in low spirits. Does he or she cry?

Yes                  No

Frequency:

Severity:

### Anxiety

Is the patient nervous, worried or frightened for no apparent reason?

Yes                  No

Frequency:

Severity:



## Pain Assessment in Advanced Dementia [3]

	0	1	2
<b>Breathing independent of vocalisation</b>	Normal	Occasional laboured breathing. Short period of hyperventilation	Noisy laboured breathing. Long period of hyperventilation. Cheyne-Stokes respirations
<b>Negative vocalisation</b>	None	Occasional moan or groan Low-level speech with a negative or disapproving quality	Repeated troubled calling out. Loud moaning or groaning. Crying
<b>Facial expression</b>	Smiling or inexpressive	Sad. Frightened. Frown	Facial grimacing
<b>Body language</b>	Relaxed	Tense Distressed pacing. Fidgeting	Rigid. Fists clenched. Knees pulled up Pulling or pushing away. Striking out
<b>Consolability</b>	No need to console	Distracted or reassured by voice or touch	Unable to console, distract or reassure

### Item definitions

#### Breathing

1. *Normal breathing* is characterised by effortless, quiet, rhythmic (smooth) respirations
2. *Occasional laboured breathing* is characterised by episodic burst of harsh, difficult or wearing respirations
3. *Short period of hyperventilation* is characterised by intervals of rapid deep breaths lasting a short period of time
4. *Noisy laboured breathing* is characterised by negative sounding respirations on inspiration or expiration. They may be loud, gurgling, wheezing. They appear strenuous or wearing
5. *Long period of hyperventilation* is characterised by an excessive rate and depth of respirations lasting a considerable time



6. *Cheyne-Stokes respirations* are characterised by rhythmic waxing and waning of breathing from very deep to shallow respirations with periods of apnoea (cessation of breathing)

### Negative Vocalisation

1. *None* is characterised by speech or vocalisation that has a neutral or pleasant quality
2. *Occasional moan or groan* is characterised by mournful or murmuring sounds, wails or laments. Groaning is characterised by louder than usual inarticulate involuntary sounds, often abruptly beginning and ending
3. *Low level speech with a negative or disapproving quality* is characterised by muttering, mumbling, whining, grumbling or swearing in a low volume with a complaining, sarcastic or caustic tone.
4. *Repeated troubled calling out* is characterised by phrases or words being used over and over in a tone that suggests anxiety, uneasiness or distress
5. *Loud moaning or groaning* is characterised by mournful or murmuring sounds, wails or laments in much louder than usual volume. Loud groaning is characterised by louder than usual inarticulate involuntary sounds, often abruptly beginning and ending
6. *Crying* is characterised by an utterance of emotion accompanied by tears. There may be sobbing or quiet weeping

### Facial expression

1. *Smiling or inexpressive*. Smiling is characterised by upturned corners of the mouth, brightening of the eyes and a look of pleasure and contentment. Inexpressive refers to a neutral, at ease, relaxed or blank look.
2. *Sad* is characterised by an unhappy, lonesome, sorrowful or dejected look. There may be tears in the eyes.
3. *Frightened* is characterised by a look of fear, alarm or heightened anxiety. Eyes appear wide open
4. *Frown* is characterised by a downturn of the corners of the mouth. Increased facial wrinkling in the forehead and around the mouth may appear
5. *Facial grimacing* is characterised by a distorted distressed look. The brow is more wrinkled as is the area around the mouth. Eyes may be squeezed shut

### Body language

1. *Relaxed* is characterised by a calm, restful, mellow appearance. The person seems to be taking it easy
2. *Tense* is characterised by a strained, apprehensive or worried appearance. The jaw may be clenched (exclude any contractures)
3. *Distressed pacing* is characterised by activity that seems unsettled. There may be fearful, worried or disturbed element present. The rate may be faster or slower.
4. *Fidgeting* is characterised by restless movement. Squirming about or wriggling in a chair may occur. Repetitive touching, tugging or rubbing body parts can also be observed.
5. *Rigid* is characterised by stiffening of the body. The arms and/or legs are tight and inflexible. The trunk may appear straight and unyielding (exclude any contractures)
6. *Fists clenched* is characterised by tightly closed hands. They may be open and closed repeatedly or held tightly shut
7. *Knees pulled up* is characterised by flexing the legs and drawing the knees up towards the chest. An overall troubled appearance (exclude any contractures)
8. *Pulling or pushing away* is characterised by resistiveness upon approach or to care. The person is trying to escape by yanking or wrenching him or herself free or shoving you away
9. *Striking out* is characterised by hitting, kicking, grabbing, punching, biting or other form of personal assault

### Consolability

1. *No need to console* is characterised by a sense of well being. The person appears content
2. *Distracted or reassured by voice or touch* is characterised by a disruption in the behaviour when the person is spoken to or touched. The behaviour stops during the period of interaction with no indication that the person is at all distressed
3. *Unable to console, distract or reassure* is characterised by the inability to sooth the person or stop the behaviour with words or actions. No amount of comforting, verbal or physical will alleviate the behaviour.

# Disability Distress Assessment Tool



Client's name:

DoB:

Gender:

Unit/ward:

NHS No:

Your name:

Date completed:

Names of others who helped complete this form:

## DisDAT is

Intended to help identify distress cues in people who because of cognitive impairment or physical illness have severely limited communication.

Designed to describe a person's usual content cues, thus enabling distress cues to be identified more clearly.

NOT a scoring tool. It documents what many staff have done instinctively for many years thus providing a record against which subtle changes can be compared. This information can be transferred with the client or patient to any environment.

Only the first step. Once distress has been identified the usual clinical decisions have to be made by professionals.

Meant to help you and your client or patient. It gives you more confidence in the observation skills you already have which in turn will help you improve the care of your client or patient.

## INSTRUCTIONS FOR USING DisDAT ARE ON THE BACK PAGE

### SUMMARY OF SIGNS AND BEHAVIOURS

#### Appearance when CONTENT

Face  
Tongue/jaw  
Skin  
Eyes

#### Appearance when DISTRESSED

Face  
Tongue/jaw  
Skin  
Eyes

#### Vocal signs when CONTENT

Sounds  
Speech

#### Vocal signs when DISTRESSED

Sounds  
Speech

#### Habits and mannerisms when CONTENT

Habits  
Mannerisms  
Comfortable distance

#### Habits and mannerisms when DISTRESSED

Habits  
Mannerisms  
Comfortable distance

#### Posture & observations when CONTENT

Posture  
Observations

#### Posture & observations when DISTRESSED

Posture  
Observations

Known triggers of distress (write here any actions or situations that usually cause or worsen distress)

## Disability Distress Assessment Tool



Please take some time to think about and observe your client's appearance and behaviours when they are both content and distressed, and describe these cues in the spaces given. We have listed words in each section to help you to describe your client or patient. You can circle the word or words that best describe the signs and behaviours when your client or patient is content and when they are distressed. Document the cues in each category and, if possible, give a fuller description in the spaces given. Your descriptions will provide you with a clearer picture of your client's 'language' of distress.

### COMMUNICATION LEVEL \*

- This person is unable to show likes or dislikes  Level 0
- This person is able to show that they like or don't like something  Level 1
- This person is able to show that they want more, or have had enough of something  Level 2
- This person is able to show anticipation for their like or dislike of something  Level 3
- This person is able to communicate detail, qualify, specify and/or indicate opinions  Level 4

\* This is adapted from the Kidderminster Curriculum for Children and Adults with Profound Multiple Learning Difficulty (Jones, 1994, National Postage Association).

### FACIAL SIGNS

#### Appearance

Information / instructions	Appearance when content	Appearance when distressed
<b>Ring</b> the words that best describe the facial appearance	Passive    Laugh    Smile    Frown Grimace            Startled    Frightened Other:	Passive    Laugh    Smile    Frown Grimace            Startled    Frightened Other:

#### Jaw movement

Information / instructions	Movement when content	Movement when distressed
<b>Ring</b> the words that best describe the jaw movement	Relaxed            Drooping            Grinding Biting                Rigid Other:	Relaxed            Drooping            Grinding Biting                Rigid Other:

#### Appearance of eyes

Information / instructions	Appearance when content	Appearance when distressed
<b>Ring</b> the words that best describe the appearance	Good eye contact            Little eye contact Avoiding eye contact            Closed eyes Staring            Sleepy eyes 'Smiling'            Winking            Vacant Tears            Dilated pupils Other:	Good eye contact            Little eye contact Avoiding eye contact            Closed eyes Staring            Sleepy eyes 'Smiling'            Winking            Vacant Tears            Dilated pupils Other:

### SKIN APPEARANCE

Information / instructions	Appearance when content	Appearance when distressed
<b>Ring</b> the words that best describe the appearance	Normal            Pale            Flushed Sweaty            Clammy Other:	Normal            Pale            Flushed Sweaty            Clammy Other:

**VOCAL SOUNDS** (NB. The sounds that a person makes are not always linked to their feelings)

Information / instructions	Sounds when content	Sounds when distressed
<p><b>Ring</b> the words that best describe the sounds</p> <p>Write down commonly used sounds (write it as it sounds; 'bzz', 'eeiow', 'tetetetete'):</p> <p>.....</p> <p>.....</p> <p>.....</p>	<p>Volume: high medium low</p> <p>Pitch: high medium low</p> <p>Duration: short intermittent long</p> <p>Description of sound / vocalisation: Cry out Wail Scream laugh</p> <p>Groan / moan shout Gurgle</p> <p>Other:</p>	<p>Volume: high medium low</p> <p>Pitch: high medium low</p> <p>Duration: short intermittent long</p> <p>Description of sound / vocalisation: Cry out Wail Scream laugh</p> <p>Groan / moan shout Gurgle</p> <p>Other:</p>

**SPEECH**

Information / instructions	Words when content	Words when distressed
<p>Write down commonly used words and phrases. If no words are spoken, write NONE</p>		
<p><b>Ring</b> the words which best describe the speech</p>	<p>Clear Stutters Slurred Unclear</p> <p>Muttering Fast Slow</p> <p>Loud Soft Whisper</p> <p>Other:</p>	<p>Clear Stutters Slurred Unclear</p> <p>Muttering Fast Slow</p> <p>Loud Soft Whisper</p> <p>Other:</p>

**HABITS & MANNERISMS**

Information / instructions	Habits and mannerisms when content	Habits and mannerisms when distressed
<p>Write down the habits or mannerisms, eg. "Rocks when sitting"</p>		
<p>Write down any special comforters, possessions or toys this person prefers.</p>		
<p>Please <b>Ring</b> the statements which best describe how comfortable this person is with other people being physically close by</p>	<p>Close with strangers</p> <p>Close only if known</p> <p>No one allowed close</p> <p>Withdraws if touched</p>	<p>Close with strangers</p> <p>Close only if known</p> <p>No one allowed close</p> <p>Withdraws if touched</p>

**BODY POSTURE**

Information / instructions	Posture when content	Posture when distressed
<p><b>Ring</b> the words that best describe how this person sits and stands.</p>	<p>Normal Rigid Floppy</p> <p>Jerky Slumped Restless</p> <p>Tense Still Able to adjust position</p> <p>Leans to side Poor head control</p> <p>Way of walking: Normal / Abnormal</p> <p>Other:</p>	<p>Normal Rigid Floppy</p> <p>Jerky Slumped Restless</p> <p>Tense Still Able to adjust position</p> <p>Leans to side Poor head control</p> <p>Way of walking: Normal / Abnormal</p> <p>Other:</p>

**BODY OBSERVATIONS**

Information / instructions	Observations when content	Observations when distressed
<p>Describe the pulse, breathing, sleep, appetite and usual eating pattern, eg. eats very quickly, takes a long time with main course, eats puddings quickly, "picky".</p>	<p>Pulse:</p> <p>Breathing:</p> <p>Sleep:</p> <p>Appetite:</p> <p>Eating pattern:</p>	<p>Pulse:</p> <p>Breathing:</p> <p>Sleep:</p> <p>Appetite:</p> <p>Eating pattern:</p>

## Information and Instructions

### When to use DisDAT

*When the team believes the client is NOT distressed*

The use of DisDAT is optional, but it can be used as a

- baseline assessment document
- transfer document for other teams

*When the team believes the client IS distressed*

If DisDAT has already been completed it can be used to compare the present signs and behaviours with previous observations documented on DisDAT. It then serves as a baseline to monitor change.

If DisDAT has not been completed:

- When the client is well known DisDAT can be used to document previous content signs and behaviours and compare these with the current observations
- When the client or the distress is new to the team, DisDAT can be used document the present signs and behaviours to act a baseline to monitor change.

### How to use DisDAT

- Observe the client when content and when distressed- document this on the inside pages. *Anyone who cares for the patient can do this.*
- Observe the context in which distress is occurring.
- Use the clinical decision distress checklist on this page to assess the possible cause.
- Treat or manage the likeliest cause of the distress.
- The monitoring sheet is a separate sheet, which may help if you want to see how the distress changes over time.
- The goal is a reduction the number or severity of distress signs and behaviours.

### Remember

- Most information comes from the whole team in partnership with the family.
- The assessment form need not be completed all at once and may take a period of time.
- Reassessment is essential as the needs of the client or patient may change due to improvement or deterioration.
- Distress can be emotional, physical or psychological. What is a minor issue for one person can be major to another.
- If signs are recognised early then suitable interventions can be put in place to avoid a crisis.

### Clinical decision distress checklist

Use this to help decide the cause of the distress

#### Is the new sign or behaviour?

- Repeated rapidly?  
*Consider pleuritic pain (in time with breathing)*  
*Consider colic (comes and goes every few minutes)*  
*Consider repetitive movement due to boredom or fear.*
- Associated with breathing?  
*Consider: infection, COPD, pleural effusion, tumour*
- Worsened or precipitated by movement?  
*Consider: movement-related pains*
- Related to eating?  
*Consider: food refusal through illness, fear or depression*  
*Consider: food refusal because of swallowing problems*  
*Consider: upper GI problems (oral hygiene, peptic ulcer, dyspepsia) or abdominal problems.*
- Related to a specific situation?  
*Consider: frightening or painful situations.*
- Associated with vomiting?  
*Consider: causes of nausea and vomiting.*
- Associated with elimination (urine or faecal)?  
*Consider: urinary problems (infection, retention)*  
*Consider: GI problems (diarrhoea, constipation)*
- Present in a normally comfortable position or situation?  
*Consider: anxiety, depression, pains at rest (eg. colic, neuralgia), infection, nausea.*

If you require any help or further information regarding DisDAT please contact:  
Lynn Gibson 01670 394 260  
Dorothy Matthews 01670 394 808  
Dr. Claud Regnard 0191 285 0063 or e-mail on [claudregnard@stoswaldsuk.org](mailto:claudregnard@stoswaldsuk.org)

Northgate & Prudhoe NHS Trust Palliative Care Team  
and St. Oswald's Hospice

#### Further reading

Regnard C, Matthews D, Gibson L, Clarke C, Watson B  
Difficulties in identifying distress and its causes in people with severe communication problems. *International Journal of Palliative Nursing*, 2003, 9(3): 173-6.

**Distress may be hidden,  
but it is never silent**

(r14a) DisDAT Monitor Patient: \_\_\_\_\_ Start month: \_\_\_\_\_ Year: \_\_\_\_\_

- |     |  |   |
|-----|--|---|
| Q 1 | Is the sign/behaviour of distress present? | If No, score 0; if Yes, go to next question |
| Q 2 | Is it moderately affecting on the day?     | If No, score 1; if Yes, go to next question |
| Q 3 | Is it dominating the day?                  | If No, score 2; if Yes, score 3             |

Score based on PACA (distress 7)

Patient sign or behaviour of distress: (EXAMPLE): grimaces

DATE	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	30	1	2	3	4	5	6	7
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2																										
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DATE or TIME																										
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Patient sign or behaviour of distress:

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TOTAL score

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## **Oral presentations**

I have delivered the following oral presentations:-

**“The assessment of good practice in pain management in severe dementia: a pilot study”**

DisDAT conference

Pollock Halls, University of Edinburgh

30<sup>th</sup> October 2006

**“Palliative care for patients with dementia”**

Current Issues in Palliative Care

Institute of Physics, London

3<sup>rd</sup> May 2007

**“Assessing and managing pain in dementia”**

Building Bridges conference, Supportive, Palliative and End of Life care for people with dementia.

Gosforth Park Hotel, Newcastle

5<sup>th</sup> July 2007

**“Pain and Dementia”**

Agile National Conference - Rehabilitation Perspectives in Dementia Care

Centre for Life, Newcastle

14<sup>th</sup> September 2007

**“Assessing pain in severe dementia”**

NHS Do Once and Share (DOAS) project

International Conference Centre, Harrogate

3<sup>rd</sup> October 2007



**“Assessing Pain in Advanced Dementia”**

**British Pain Society, Pain in Older Adults group**

**University of Teesside**

**23<sup>rd</sup> January 2008**

### **Poster presentations**

1. Jordan A I, Hughes J C, O'Brien J T. "The assessment and management of pain in severe dementia". 7<sup>th</sup> November 2006. UK Dementia Conference, Bournemouth
2. Jordan A I, Hughes J C, O'Brien J T. "The assessment and management of pain in severe dementia". 2nd March 2007. Marie Curie Palliative Care Research Conference, London

### **Publications**

1. Hughes J.C., Jolley D., Jordan A., Sampson E.L., *Palliative care in dementia: issues and evidence*. *Advances in Psychiatric Treatment*, 2007. **13**: p. 251-260
2. Jordan A.I., Regnard C., Hughes, J.C., *Hidden Pain or Hidden Evidence?* *Journal of Pain and Symptom Management*, 2007. **33** (6): p. 658-9

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**Newcastle & North Tyneside Local Research Ethics Committee 2**

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29 July 2005

Dr Julian C Hughes  
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Dear Dr Hughes

**Full title of study:**           **The Assessment of Good Practice in Pain Management in Severe Dementia: A Pilot Study**  
**REC reference number:**       **05/Q0906/111**

Thank you for your letter received on 28 July 2005, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The favourable opinion applies to the research sites listed on the attached form.

**Conditions of approval**

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	4.1	26 May 2005
Investigator CV	JCH	25 May 2005
Protocol	JCH/AM	20 May 2005
Covering Letter		26 May 2005
Summary/Synopsis		(None Specified)
Letter from Sponsor		10 April 2005
Peer Review		25 February 2005
Statistician Comments		(None Specified)

GP/Consultant Information Sheets	Draft 3	21 July 2005
Participant Information Sheet	Draft 3	22 July 2005
Participant Information Sheet Relatives	Draft 2	26 May 2005
Participant Information Sheet For Care Homes	Draft 2	26 May 2005
Participant Consent Form Nursing	Draft 2	26 May 2005
Participant Consent Form	Draft 2	26 May 2005
Response to Request for Further Information		(None Specified)
Other	Draft 1 Assent Form	22 July 2005
Letter to next of kin	Draft 2	26 May 2005
Assent Form for Relatives	Draft 2	26 May 2005
Reply to Sponsor		27 April 2005
Response to Reviewer	JCH/AM	21 March 2005
PAINAD Scale		(None Specified)
Abbey Pain Scale		(None Specified)
Cornell Scale		(None Specified)

### Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

### Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

### Statement of compliance

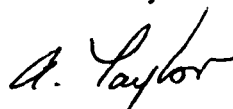
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q0906/111

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project,

Yours sincerely



Mr P Stevenson  
Vice Chair

Email: anne.taylor2@ncl.ac.uk

Enclosures: Standard approval conditions  
Site approval form (SF1)