UNIVERSITY OF DERBY

EXPLORING OBSERVATIONAL PAIN ASSESSMENT TOOLS FOR INDIVIDUALS WITH MODERATE-TO-SEVERE DEMENTIA

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Table of Contents

List of Tables and Figures

Tables

Figures

Abbreviations

APS	Abbey Pain Scale
ADD	Assessment of Discomfort in Dementia
ADL	Activities of Daily Living
AGS	American Geriatric Society
BPSD	Behavioural and Psychological Symptoms of Dementia
CASP	Critical Appraisal Skills Programme
CNPI	Checklist on Nonverbal Pain Indicators
CPAT	Certified Nurse Assistant Pain Assessment Tool
DBS	Discomfort Behaviour Scale
DS-DAT	Discomfort Scale-Dementia of the Alzheimer's Type
DSM-5	Diagnostic and Statistical Manual 5
ePAT	Electronic Pain Assessment Technology
EPCA-2	Elderly Pain Caring Assessment 2
FACS	Facial Action Coding System
FLACC	Face, Legs, Activity, Cry and Consolability Pain Assessment Tool
FPS	Facial Pain Scale
MMSE	Mini Mental State Examination
MOBID	Mobilization-Observation-Behaviour-Intensity-Dementia Pain Scale
MOBID-2	Mobilization-Observation-Behaviour-Intensity-Dementia Pain Scale 2
NCD	Neurocognitive disorder
NOPPAIN	Nursing Assistant-Administered Instrument to Assess Pain in Demented Individuals
NRS	Numeric Rating Scale
PACSLAC	Pain Assessment Checklist for Seniors with Limited Ability to Communicate
PADE	Pain Assessment for the Dementing Elderly
PAINAD	Pain Assessment in Advanced Dementia
PAINE	Pain Assessment in Noncommunicative Elderly
PBOICIE	Pain Behaviours for Osteoarthritis Instrument for Cognitively Impaired Elders
POAKS	Pain in Older Adults Knowledge Survey
QoL	Quality of Life
TIDieR	Template for Intervention Description and Replication
VAS	Visual Analogue Scale
COM-B	Capability, Opportunity, Motivation and Behaviour
VRS	Verbal Rating Scale

Preface

The work contained within this thesis has been solely authored by the doctoral candidate, with only guidance and direction given by the doctoral supervisors. Where work has been submitted for publication and contained within this thesis, the candidate is the primary author. The programme of research conducted for this thesis, the results obtained, and the wider reading and resulting thoughts and conclusions have been disseminated through various channels and are listed below:

Conferences:

Babicova, I. (May, 2017). A Research into Validity, Accuracy and Feasibility of Electronic Pain Assessment Tool (ePAT) for People with Dementia in UK Care Homes. *2017 Postgraduate Research Conference, University of Derby, Derby.*

Babicova, I. (September, 2018). Pain in People with Dementia: A Systematic Review of the Effectiveness of Observational Pain Assessment Tools. *2018 East Midlands Doctoral Network Conference, Bishop Grosseteste University, Lincoln.*

Abstract

The global increase in the prevalence of dementia has provoked a multidisciplinary response from researchers, policymakers, educators and clinical sectors. There are many important aspects of care, which need to be considered when looking after an individual with dementia. One such aspect of care, and a fundamental human right, is appropriate pain treatment and management. Due to the progressive neurodegenerative nature of dementia, individuals in the moderate to severe stages of the condition are often unable to self-report their pain, therefore health professionals rely on the use of observational pain assessments. Unfortunately, pain continues to be under-recognised, underestimated and under-treated in people living with moderate-to-severe dementia. There is, therefore, a need to enhance observational pain assessment, to ensure that appropriate pain treatment and management is implemented.

This thesis set out the following aim and objectives: Aim: To examine the psychometric properties, in terms of validity and reliability, of observational pain assessment tools for people living with moderate-to-severe dementia. Objective (a) to conduct a systematic review to further investigate the current state of observational pain assessment tools. Objective (b) to explore feasibility and use of observational pain assessment tools, specifically the Abbey Pain Scale and the PainChek®, in a UK care home setting. Objective (c) to validate and evaluate the psychometric properties of PainChek® in a UK care home. Objective (d) to investigate three case studies of individuals living with dementia who demonstrated atypical pain behaviours. The aim and objectives were accomplished by conducting four studies.

The first study was a systematic review which examined the psychometric properties of observational pain assessment tools. The results from the seventeen studies which met criteria for inclusion indicated a highly heterogeneous, indicating that validity and reliability measures, such as inter-rater reliability or concurrent validity, were highly diverse across observational tools which were tested for psychometric qualities.

The second study utilised exploratory qualitative methods to explore perceived feasibility of two observational pain assessment tools; Abbey Pain Scale and PainChek®. Transcripts from the semi-structured interviews were analysed using a thematic analysis.

Four main themes were identified; strengths of the Abbey Pain Scale, limitations of the Abbey Pain Scale, strengths of PainChek®, limitations of PainChek® and critical factors of pain assessment.

The third study focused on validating PainChek®; a semi-automated observational pain assessment tool in a UK care home. Twenty-two participants diagnosed with dementia and a painful condition were recruited. Over a period of sixteen weeks, psychometric properties in terms of validity and reliability of PainChek® were evaluated by direct comparison to the Abbey Pain Scale. Three hundred and two paired pain assessments were completed. The analysis of the data revealed excellent validity and reliability results, demonstrating that PainChek® would be a suitable tool to asses' pain in people with dementia in UK care homes.

The fourth and final study explored three case studies in depth. During the data collection in the previous study, three participants were consistently expressing atypical and unexpected pain behaviours. The investigation into the three individual case studies has highlighted the importance and growing need for increasing interprofessional education and learning, and a consideration of how uncommon expressions of pain could hinder the accuracy of pain assessment.

The research conducted for this PhD thesis reiterated the on-going issue with under-recognition, underestimation and under-treatment of pain in people with dementia. The overall results collectively investigated and contributed findings towards the current knowledge of pain assessment in people with moderate to advanced dementia, by presenting an in-depth mixed-methods approach. In addition, the results from this thesis demonstrated excellent psychometric properties of PainChek® in a UK care home and explored the current limitations of pain assessment and offered possible solutions. To prevent poor treatment and management of pain in individuals with dementia, regular and accurate use of observational pain assessment tools is recommended. Finally, while feasibility and appropriateness of the use of the PainChek® were explored, further research focusing on implementation is needed to investigate the pragmatic and practical aspects of using an electronic device in care homes.

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After completing my BSc in Psychology at the University of Derby in 2016, I would have never thought that just over three years later I will be handing in a PhD thesis in a topic area I am extremely passionate about. My PhD journey was not always easy, but I wouldn't be able to get this far without the incredible help and support I have received from many people over the years. First, I would like to express my deepest and sincerest gratitude to my super-supervisors Dr Ainslea Cross, Professor Dawn Forman and Assistant Professor Kreshnik Hoti. Thank you for giving me the opportunity to do research and for your invaluable guidance, support and encouragement from the very start. Your expertise in research and continuous belief in me has inspired me on many occasions, especially during tough days. I would also like to thank Professor David Sheffield, for your support and statistical advice. I am forever grateful for the time and effort you all have invested in me.

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I wish to dedicate this thesis in loving memory of my grandma Alena. I'd like to think that she would have been proud.

1 Chapter One - Introduction

In 2012 dementia became a public health priority (World Health Organisation and Alzheimer's Disease International, 2012) as a result of a rapidly ageing population. Since 2010, the number of individuals diagnosed with dementia has increased from 36 million to 50 million (World Health Organisation, 2019), with the current trend suggesting 10 million new diagnoses every year. Over the next 38 years, projected growth suggests a 156% increase of dementia diagnoses (Alzheimer's Society, 2017; World Health Organisation, 2017; Prince et al., 2015).

Prevalence of pain in people with dementia ranges considerably. Between 28% to 85% of individuals living with dementia experience chronic or acute pain on daily basis (Català et al., 2002; Hunt et al., 2015; McClean & Higginbotham, 2002; Monroe et al., 2014; Patel, Guralnik, Dansie, & Turk, 2013). The wide range of pain prevalence reported across studies could be explained by factors such as severity of cognitive impairment (Proctor & Hirdes, 2001) or the presence of additional comorbidities (Leong, Farrell, Helme, & Gibson, 2007). However, regardless of the factors which may have influenced the reported prevalence of pain, all pain should be recognised, treated and managed appropriately.

This, however is often not the case in dementia, as research continues to demonstrate that pain in dementia is still under-recognised, underestimated and under-treated (Peisah, Weaver, Wong, & Strukovski, 2014; Seitz et al., 2014). Appropriate treatment and management of pain is a fundamental human right (Somerville, 2001) and therefore not providing it is unethical. In addition, persistent and untreated pain in dementia has been linked with increased level of cognitive deterioration (Whitlock et al., 2017) which may lead to premature death. Thus, it is important that this area of pain and dementia is not only further researched, but also that the focus of the research is to improve pain recognition, assessment, treatment and management in the people living with dementia.

In addition, in 2015, the Dementia Policy Team along with the government have developed The Prime Minister's Challenge on Dementia 2020 (Department of Health, 2015). Within this challenge, the key focus was for the UK to become the lead country in the world for dementia care and support, the best country for people with dementia and their carers and families, and the best country to undertake research into dementia and other neurodegenerative disorders. While the Prime Minister's Challenge on Dementia focuses on the "living well" and "dying well" aspects of dementia, it does not consider how pain affects quality of life in those living with dementia. Pain, as well as its assessment, treatment and management should be considered in the implementation plan in the future, as it directly links to ethical considerations. The current policy in the UK for assessment of the presence and severity of pain in people with dementia as outlined by the National Institute for Health and Care Excellence (NICE) guidelines is to "consider using a structured observational pain assessment tool" (NICE, 2018, p. 28). This concerning and unclear policy does not encourage health professionals to use observational pain assessment tools regularly, nor does it recommend a specific tool. In addition, in a 2017 report, the NHS Improvement organisation which actively works with NHS England to deliver improved care for patients, has stated there is an inconsistent application of good practice for person-centred care (NHS Improvement, 2017).

Therefore, the topic of observational pain assessment in moderate-to-severe dementia was explored, with the hope that the research undertaken within this thesis will aid not only as an original contribution towards current knowledge, but also offer more understanding of why pain is not treated correctly. To do so, the following aim and objectives have been developed:

Aim: To examine the psychometric properties, specifically validity and reliability, of observational pain assessment tools for people living with moderate-to-severe dementia.

Objective (a): To conduct a systematic review to further investigate the current state of observational pain assessment tools used in care homes.

Objective (b): To explore feasibility and use of observational pain assessment tools, specifically the Abbey Pain Scale and the PainChek®, in a UK care home setting.

Objective (c): To validate and evaluate psychometric properties of PainChek® in a UK care home.

Objective (d): To investigate three case studies of individuals living with dementia who demonstrated atypical pain behaviours.

In order to meet the main aim of this PhD thesis, a mixed-methods approach was adopted and the following four studies were conducted; a systematic review, a qualitative exploratory study, a quantitative validation study, and case studies. All four studies focused on pain in people living with dementia, specifically the psychometric properties of observational pain assessment tools used to assess pain in non-verbal individuals with dementia. Psychometric properties, in this case, focuses on reported validity and reliability of observational pain assessment tools, and their appropriateness of use within settings such as care homes. The following sub-sections provide a brief outline of each chapter in this thesis.

Chapter Two: Chapter two begins with defining dementia, exploring the types of dementia and briefly outlining prevalence, comorbidity and perceived quality of life. The chapter then presents a literature review of pain assessment, with a particular focus on observational pain assessment tools developed specifically for people with dementia. Within this review, the importance of training, knowledge and education of pain assessment and dementia will be briefly explored. This is then followed with introduction of some of the key issues in this topic area such as under-recognition, underestimation and under-treatment of pain in people living with dementia. The chapter ends with a clearly stated rationale for the studies undertaken in this thesis, states the aim of the thesis overall and explains how the aim is going to be achieved with four detailed objectives.

Chapter Three: Chapter three outlines the methodology used throughout the four studies. As the studies in this thesis utilised a mixed methods design, each study is briefly introduced and outlined individually. The main aims and objectives and the

analytic strategy are stated for each of the four studies. All tools utilised within the studies in this thesis, such as the Abbey Pain Scale (Abbey et al., 2004) or the Mini-Mental State Examination (Folstein, Folstein, & Mchugh, 1975) are discussed in terms of their strengths, limitations and their appropriateness for the study design and aims. A detailed breakdown of the steps taken to process, analyse and report data in Chapters four, five, six and seven will be outlined in this chapter.

Chapter Four: The first of the four studies; a Systematic Review, will be introduced in this chapter. First, this chapter will focus on reiterating some of the key issues with observational pain assessment tools which have previously been outlined in chapter two. Then, the method in terms of inclusion and exclusion criteria, search strategy, and screening phases will be outlined. This will then be followed by risk of bias assessment and quality assurance screening of each article which met the criteria for inclusion in the systematic review. Two analyses will then be conducted; a meta-analysis which will investigate the psychometric properties (validity and reliability) of observational pain assessment tools identified in studies in the systematic review, and a narrative review which will look at other elements such as positive health outcomes or the number of pain domains included within each tool will be investigated.

Chapter Five: Chapter five introduces the second study in this PhD thesis, which investigates feasibility of the Abbey Pain Scale and the PainChek® within care home staff (i.e. registered nurses, nursing associates and other roles within care homes) by conducting qualitative semi-structured interviews. First, a brief introduction will be outlined, explaining the rationale behind this study followed by an outline of the methodology undertaken. The four main identified themes and their sub-themes will be outlined, and discussed in terms of perceived strengths, weaknesses and feasibility of observational pain assessments. The implications of the findings and their importance of investigating feasibility when developing new pain observational pain assessment tools are will then be discussed.

Chapter Six: In this chapter, PainChek® will be further validated and psychometric properties will be evaluated in terms of psychometric properties (validity and reliability) in a UK care home. At first, a literature review of previous validation studies will be presented. Then, an outline of the method in terms of design, setting, recruitment of a

care home, a nurse and participants, materials, procedure and analytic strategy will be outlined. The validation process involved a direct comparison of the PainChek® to another observational pain assessment tool - the Abbey Pain Scale. The results from this study have demonstrated excellent validity and reliability scores of PainChek® suggesting it would be an appropriate tool to use in practice. Lastly, during the observational and data collection phases of this study, three participants have demonstrated atypical behaviours when they were experiencing pain. The atypical behaviours and their implications will be discussed in chapter seven.

Chapter Seven: The participants who have shown behaviours which were unexpected and atypical will be introduced and discussed in this chapter. Three participants will be examined in more depth, in terms of how atypical behaviour could hinder the accuracy of observational pain assessment tools. After all three case studies have been introduced; the chapter will focus on underpinning the causes of the atypical pain behaviours to relevant theory and research. This chapter will also outline key problems with behaviours which are not expected, followed by proposing solutions to the key problems. The chapter will end by reiterating the importance of case studies in research and discuss the implications and applications of the findings to practice.

Chapter Eight: The final chapter of this PhD thesis reflects the journey taken to achieve the main thesis aim to examine and compare the psychometric properties of observational pain assessment tools for people living with moderate-to-severe dementia in care homes. The chapter summarises the main findings of the four studies and reflects on methodological strengths and limitations. Unique findings are also discussed, which focus on any observations or results which were not expected but became interesting and worthy to report throughout this PhD journey. Then implications and applications of findings to practice are outlined and original contribution of the research are discussed.

2 Chapter Two - Literature Review

2.1 Overview

This literature review summarises the key evidence about pain and dementia and provides insights into some of the main issues surrounding pain recognition, assessment, treatment and management in people with dementia. Observational pain assessment tools currently available, their strengths and weaknesses, the importance of inclusion of multiple pain domains in these tools and the pain assessment process itself will be explored in this chapter. In addition, this literature review also explores the role education and training of pain and pain tools have on accuracy of pain recognition and assessment, as well as a critical evaluation of accurate and inaccurate pain recognition and assessment and the consequences of this.

The three major areas critically discussed in this literature review were:

- The observational pain assessment tools which enable assessment of pain in people with moderate to severe dementia
- The key elements which help increase the accuracy of pain recognition and therefore pain treatment and management
- The consequences of inaccurately assessed and treated pain in people with moderate to severe dementia

The literature review will also investigate in more detail the consequences inaccurate pain assessment has on deterioration and cognitive impairment, quality of life and the current state of pain recognition, assessment, treatment and management overall.

2.1.1 What is dementia?

Dementia is an umbrella term for a cluster of progressive neurological symptoms

which include memory loss, difficulties with thinking, language, problem-solving or other symptoms associated with cognitive decline (Dementia UK, 2017). There are many types of dementia; the most common types are Alzheimer's Disease, Vascular Dementia, Dementia with Lewy Bodies and Frontotemporal Dementia.

The Diagnostic and Statistical Manual of Mental Health Disorders fifth edition (DSM-5) uses the term Neurocognitive disorder (NCD) to refer to dementia, although the manual suggests that the term dementia is still an acceptable alternative to use (American Psychiatric Association, 2019). Unlike the previous version of the Diagnostic and Statistical Manual, the DSM-5 now recognises two types of NCD; mild and major. The term neurocognitive consists of the word "neuro" which emphasises disrupted brain function and the term "cognitive" which refers to thinking and related processes. The DSM-5 also provides a list of cognitive domains, to help establish presence and severity of NCD impairment. There are six cognitive domains which may be affected in mild or major NCD:

1) Complex attention, which consists of sustained attention, divided attention, selective attention and information processing speed

2) Executive function, which consists of planning, decision making, working memory, responding to feedback, inhibition and mental flexibility

3) Learning and memory, which consists of free recall, cued recall, recognition memory, semantic and autobiographical long-term memory and implicit learning

4) Language, which consists of object naming, word finding, fluency, grammar and syntax and receptive language

5) Perceptual-motor function, which consists of visual perception, visuo-constructional reasoning and perceptual-motor coordination
6) Social cognition, which consists of recognition of emotions, theory of mind and insight

Dementia severity is classified as either mild, moderate or severe by the burden of cognitive decline (World Health Organization, 2012).

Mild – cognitive decline is severe enough to limit functional activities, but independent living is possible.

Moderate – The deficit is severe enough to seriously inhibit functional activity. Familiar material is retained, but independent living is not possible without support.

Severe – complete inability to retain new information. Assistance is required for all activities of daily living. Communication is limited to single words and sounds.

2.1.1.1 Prevalence of dementia and pain

As a result of ageing populations and a significant increase of individuals diagnosed with the condition every year, by 2012 dementia had become a public priority (World Health Organization and Alzheimer's Disease International, 2012).

An individual in the world develops dementia every 3 seconds (Alzheimer's Disease International, 2017). Since 2010, the amount of individuals diagnosed with dementia has increased from 36 million (Alzheimer's Disease International, 2012), to 47 million in 2015, (Prince et al., 2015) and 50 million in 2019 (World Health Organisation, 2019). The number of people living with dementia is estimated to double every 20 years, with the current trends indicating 10 million new cases of dementia worldwide every year, suggesting an increase of 156% over the next 38 years. In 2015, 9.8 million people with dementia lived in East Asia, 7.4 million in Western Europe, 5.1 million in South Asia and 4.8 million in North America (Prince et al., 2015). Further to this, over the next 15 years it is estimated that these numbers will increase by 28% in Europe, 52% in North America, 52% in the southern Latin America zone and 56% in Asian Pacific Countries.

Up to 69% of individuals living in care or residential homes have a diagnosis of dementia (Prince et al., 2014). The reported pain prevalence in people with dementia varies considerably, due to differences in methodology, participant cohort, setting and type of pain (McAuliffe, Brown, & Fetherstonhaugh, 2012). Depending on the observational pain assessment tool used, the range of pain prevalence varies from 38.4% of people experiencing pain to 83.8% of people experiencing pain (Björkman, Sorva, & Tilvis, 2008). Furthermore, Chen, Lin, & Watson (2010) found pain prevalence varies from 34% to 48% in dementia care units. The wide range of pain prevalence reported across studies could be explained by several factors. For example, some studies reported that females are more likely to report pain compared to males (McClean & Higginbotham, 2002), meaning that the pain prevalence reported by researchers could vary due to the male to female ratio present in settings where data collection occurred. Other factors which could have affected the reported prevalence are the severity of cognitive impairment in nursing home residents (Proctor & Hirdes, 2001) or the number of comorbidities experienced by the individual (Leong et al., 2007). Thus, it is difficult to precisely pinpoint the prevalence of pain in a population living with dementia.

2.1.1.2 Cognitive and non-cognitive symptoms of dementia

Individuals who develop dementia will develop cognitive and non-cognitive symptoms, which will worsen over time due to the progression of the condition. There are many factors which can influence the onset, development and severity of symptoms of dementia. Some of these factors include personality, general health, or social situation (Alzheimer's Disease International, 2018). Because of this, the symptoms and their severity often vary not just between types of dementia, but also from individual to individual.

Cognitive symptoms of dementia refer to symptoms which are largely to do with thinking and memory. These often include problems with day-to-day memory such as difficulty in recalling recent events, focusing, planning or organising, which also includes problem solving, decision making and problems with carrying out a sequential

task, following a conversation, finding the right word or other language difficulties, visuospatial skills and orientation (Alzheimer's Society, 2017b).

Non-cognitive symptoms of dementia are often referred to as Behavioural and Psychological Symptoms of Dementia (BPSD) and include symptoms such as hallucinations, delusions, affective disturbances, disturbed behaviour such as aggression, anxiety, depression and other behaviours (Cerejeira, Lagarto, & Mukaetova-Ladinska, 2012). BPSD are commonly associated with cognitive decline in Alzheimer's disease and other dementias. The symptoms are usually present from early stages of dementia, and gradually worsen over time, therefore negatively impacting life and the progress of the condition in individuals living with dementia (David et al., 2010; Fernández, Gobartt, & Balañá, 2010).The majority of people living with dementia show characteristics and symptoms of BPSD (Taemeeyapradit, Udomittipong, & Tepparak, 2014). Robert et al. (2005) states that the most commonly observed symptoms of BPSD are depression (44.9%) anxiety (42%), agitation (35%), irritability (30.6%), aberrant motor behaviour (24.7%), delusions (22%), appetite disturbances (21.4%), sleep disturbances (14.3%), disinhibition (12.4%), hallucinations (8.5%) and euphoria (6.8%).

2.2 Comorbidity

Individuals living with dementia have on average two to eight additional physical and mental comorbidities (Schubert et al., 2006), with the two most frequent being hypertension and diabetes (Poblador-Plou et al., 2014). Additionally, individuals living with dementia also experience chronic pain conditions which are predominantly but not exclusively related to the musculoskeletal system, such as arthritis or osteoporosis (International Osteoporosis Foundation, 2017), or psychological pain (e.g. as a result of stress or bereavement). Some of the most reported causes of pain in people with dementia include osteoarthritis, osteoporosis, fractures, constipation, urinary retention, neuropathy and pain associated with vascular disease (Reynish, 2017). Furthermore, as a result of high prevalence of pain, comorbidities and a wide range of chronic conditions, a high proportion of residents living with advanced dementia experience pain in their last weeks of life (Ma et al., 2013; Van Der Steen, 2010).

Advanced stages of dementia are often characterised by aphasia, the progressive loss of language fluency, incorrect pronunciation and use of words and decreased comprehension (National Health Service (NHS), 2017), and therefore self-report measures are no longer valid or reliable for aphasic individuals. Consequently, behavioural and observational pain assessment tools have been developed to address the need to assess the presence and severity of pain, and are currently used by staff in settings including care homes to guide them with correct recognition and assessment of pain in those who can no longer self-report. Prior knowledge and accurate diagnosis of secondary comorbid mental and physical illnesses are crucial in pain assessment, as these can potentially hinder observational pain assessment. Non-pain medication is often prescribed to people living with dementia, to help manage comorbidities. Up to 41.3% of people living with dementia are prescribed antidepressants, and up to 34.1% antipsychotics (Stewart et al., 2014). The use of antipsychotics can severely hinder pain observation due to some of the side effects such as extrapyramidal symptoms, somnolence and abnormal gait (Lee et al., 2004), which can be mistaken for painful behaviours.

2.3 Living in care homes and Quality of life

Leading an independent lifestyle for as long as possible is important to a person living with dementia. However, once a later stage of dementia is reached and individuals are no longer able to stay safe while independently living at home, a transfer to a care home service or a nursing home setting is usually required, where they are assisted with their daily activities and needs (Alzheimer's Society, 2018). The individuals who require more assistance and care on a daily basis are more likely to have a higher level of cognitive impairment, meaning that those with a low level of cognition have a higher possibility of needing care or nursing home placement (Toot, Swinson, Devine, Challis, & Orrell, 2017). However, individuals living with dementia and their relatives can often struggle to adjust to a new caring facility or environment, which results in the preference to live independently at home for as long as possible (Sury, Burns, & Brodaty, 2018).

Although living in a care or nursing home enables individuals to live safely, some studies suggest that the residents often demonstrate low overall quality of life and mood (Hoe, Hancock, Livingston, & Orrell, 2006). Some studies have found a varying factor of perceived quality of life in individuals living with dementia (Engel, Kiely, & Mitchell, 2006). Further investigation into lower perceived quality of life after a transfer to a care home indicated that mood was a direct predictor of perceived quality of life. One of the ways in which mood can be improved and maintained is through correct pain assessment, which can consequently result in better pain management and treatment. Not managing and treating pain appropriately and accurately can decrease mood, quality of life and often even daily activities of living (Husebo, Ballard, Fritze, Sandvik & Aarsland, 2013).

While activities of daily living were not directly influenced by pain, pain negatively impacted behavioural disturbances and depression, which in turn influenced daily activities of living (Cipher & Clifford, 2004). Therefore, accurate pain management can not only reduce behavioural disturbances and depression and increase mood and quality of life, but it can also reduce symptoms of mental health comorbidities such as anxiety and depression through reducing irritation, agitation, stress, low mood and worry (Husebo, Ballard, Sandvik, Nilsen & Aarsland, 2011). It is therefore crucial to use an observational pain assessment tool which is accurate at detecting pain.

The World Health Organization (WHO) defines Quality of Life as:

> "Individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." (WHOQOL, 1996, p. 5)

The WHO's definition reflects the view that quality of life (QoL) refers to a subjective evaluation of an experience which is set by each individual and embedded in a cultural, social and environmental context. The definition reflects on personal perceived QoL and therefore QoL cannot be simply measured by factors such as health status, lifestyle, life satisfaction, mental state or well-being.

QoL of the person living with dementia, in terms of the person's wellbeing, wishes, values and needs, should be the key focus of care, to ensure a holistic approach to caring for individuals with dementia (Alzheimer Society Canada, 2017). However, in the UK, QoL measures and scales are mostly only used as part of research. Some of the most commonly used scales used to measure QoL in people with dementia, as outlined by Alzheimer's Society (2019) are; the Dementia Quality of Life Instrument (DQoL) (Brod et al., 1999) and DEMQOL (Smith et al., 2005).

Pain was found to directly impact QoL in dementia (Hendriks, Smalbrugge, Hertogh, & Van Der Steen, 2014), which reiterates the importance of correct pain recognition and assessment to enable a holistic approach to care. This was also indicated by Barca, Engedal, Laks & Selbæk (2011) who reported a correlation between QoL and wellbeing, specifically major depression, in individuals living with dementia. As such, accurate and reliable assessment of pain is needed to not only enable a holistic approach to care, but also to ensure a good QoL for those living with dementia.

2.4 Pain in dementia

Pain is a complex and subjective experience, with individuals perceiving it differently due to personal thresholds, past experiences and other factors. Previously, it was thought that people living with dementia, specifically at the later more advanced stages, either perceive and feel pain differently, feel pain less than those without dementia or do not feel pain at all. Some of the key arguments behind why people with dementia might perceive pain differently, or feel pain less severely than those without dementia, relate to the deterioration and death of brain tissue due to the progressive nature of the cognitive condition. For example, it was thought that people with dementia did not feel as much pain as the general healthy population as the result of the damage occurring to their brain, which in turn stopped them from feeling pain (Dementia Australia, 2017).

However, studies which conducted fMRI brain imaging scans suggested that the areas of dementia which become active when individuals feel pain, were just as active in

people with dementia as they were in the general healthy population (Cole et al., 2006). Therefore, it is suggested that pain perception and pain processing is not reduced in individuals living with dementia.

This apparent contradiction could potentially be explained. Research has shown that people with dementia report pain less often and therefore receive medication less often to manage their pain (Frampton, 2003). This is likely to be the case because the progressive deterioration of the brain causes individuals with dementia to gradually lose their ability to communicate their pain, which consequently results in a lower incidence of reported pain. This, however, does not mean that they experience pain less often, or less severely than the rest of the population. It is therefore vital for this population to be treated accordingly, with the help of an observational pain assessment tool to help assessors recognise, assess and treat pain more accurately.

While the research within this thesis focuses on the accuracy, validity and reliability of observational pain assessment tools in care homes, it is also important to consider the challenges highlighted within pain management frameworks and assumptions of the pain assessment and management process within acute hospital settings. Dowding et al. (2016) state that the existing models adopt a sequential or linear decision making process for pain recognition, assessment and management, which assumes that the pain assessor makes a correct judgement about the presence and severity of pain in individuals and subsequently makes an appropriate decisions about how to treat and manage the present pain. However, the Dowding et al. (2016) point out that pain recognition, assessment, treatment and management is not necessarily as linear as it has previously been outlined, making the pain assessment model far more complex. Therefore, it should be acknowledged that to enhance pain treatment and management in people with dementia many factors, other than utilising observational pain assessment tools, need to be investigated and researched. However, this thesis focuses on one of the factors and first steps involved in pain management, which is using observational pain assessment tools to assess presence and severity of pain in people living with dementia.

2.4.1 Pain assessment tools

Self-report is considered the gold standard globally for pain recognition and assessment. With the help of unilateral pain rating scales such as Visual Analogue Scale (VAS), Numeric Rating Scale (NRS), Facial Pain Scale (FPS) or Verbal Rating Scale (VRS) it is possible to obtain a self-reported pain rating from some individuals with mild to moderate dementia (McClean, 2003). However, these unilateral tools are no longer acceptable once the stage of dementia progresses and the individuals living with dementia are no longer able to use the scale effectively to indicate their severity of pain. With the progress of dementia, the ability to communicate and indicate the presence and severity of pain often diminishes. When this happens, observational pain assessment tools are used as a replacement for self-report pain rating scales. These tools are used by qualified nurses, healthcare assistants and other healthcare professionals and assessors to help them identify whether pain is present, and if so, whether this pain is mild, moderate or severe. These tools guide the assessors through focusing on specific pain domains and behaviours such as physiological changes, behavioural changes and other behaviours and facial expressions which are indicative of pain. Most observational pain assessment tools use a score-based rating scale, where a higher number usually equates to higher severity of pain. Once the assessors complete the observation and pain assessment, the score will indicate presence and severity of pain which can then be used as a guide to help the assessor make a decision whether the assessed individual needs pain medication to treat potentially present pain. The information about the presence and severity of pain can then be considered when evaluating the use and dose of pain medication. The use of these observational pain assessment tools is known to improve pain recognition in people living with dementia (Lukas, Barber, Johnson, & Gibson, 2013).

Based on the research conducted into this topic area as part of this literature review, it has become clear that over the past 25 years approximately 30 different pain assessment tools have been developed, and are used across all clinical and non-clinical settings such as hospitals, care homes and GP practices. However, there are no general guidelines or recommendations regarding which tool should be used globally. Individual clinicians and nurses usually have a preferred pain assessment tool, which can vary depending on recommendations by regional guidelines. In the

UK, the British Pain Society outlines the guidelines for observational pain assessment in older people with severe cognitive/communication impairment. However, although it has a practical suggestion for scale, which is the Abbey Pain Scale, it does not currently have a single recommendation for an observational pain assessment tool (Closs et al., 2007).

Most of the observational pain assessment tools take up to 10 minutes to observe the individual, followed by an additional 3-5 minutes to assess pain. The scales usually work on a Likert-like scale or a three-point “mild, moderate, severe” scale. Some pain assessment tools require the observer to reassess pain 1 hour after pain has been managed (by either analgesics or other interventions) or every 4-12 hours to investigate whether pain is still present and needs to be treated further.

The American Geriatrics Society recommends the use of six pain domains (see Table 2.1) for an accurate and reliable pain assessment in people who are no longer able to communicate their pain (AGS Panel on Persistent Pain in Older Persons, 2002). However, currently only two observational pain assessment tools incorporate all six domains; The Abbey Pain Scale (Abbey et al., 2004) and the Assessment of Discomfort in Dementia Protocol (ADD) (Kovach, Weissman, Griffie, Matson, & Muchka, 1999). Not assessing all pain domains outlined and recommended by the AGS could potentially be one of the barriers to accurate pain assessment.

Table 2.1. AGS Persistent Pain Domains (AGS, 2002) with pain domain examples

Pain domain	Example of behaviour
Facial expression	Slight frown; sad, frightened face Grimacing, wrinkled forehead, closed or tightened eyes Any distorted expression Rapid blinking
Vocalisation	Sighing, moaning, groaning Grunting, chanting, calling out Noisy breathing Asking for help Verbally abusive

Body movements	Rigid, tense body posture, guarding Fidgeting Increased pacing, rocking Restricted movement Gait or mobility changes
Changes in interpersonal interactions	Aggressive, combative, resisting care Decreased social interactions Socially inappropriate, disruptive Withdrawn
Changes in activity patterns or routines	Refusing food, appetite change Increase in rest periods Sleep, rest pattern changes Sudden cessation of common routines Increased wandering
Mental status change	Crying or tears Increased confusion Irritability or distress

Some of the most widely used pain assessment tools include Abbey Pain Scale, CNA Pain Assessment Tool (CPAT), Doloplus-2, Pain Assessment in Advanced Dementia (PAINAD), The Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN), Mobilisation-Observation-Behaviour-Intensity Dementia Pain Scale (MOBID), Pain Assessment Checklist for Seniors With Limited Ability (PACSLAC), and many others. Brief description of some of the most common observational pain assessment tool is outlined in see table 2.2; however these are also discussed in more depth in Chapter 4.

While many observational tools are available to help assessors recognise and assess pain in those who can no longer communicate it effectively, it is important to note that some of the tools available for assessors do not focus directly on pain and pain domains. Some tools, such as the Disability Distress Assessment Tool (Dis DAT) (Regnard et al., 2007) focus on distress rather than pain and were therefore not included in table 2.2. Although pain and distress are closely linked and often if a person

is experiencing pain they are also likely to be in distress, there are some conceptual differences which need to be considered in this context. Jordan, Regnard, O'Brien & Hughes (2011) defined the key differences between pain and discomfort, suggesting that pain is defined in terms of a physical insult to tissues causing stimulation of nociceptors, whereas distress is an over-arching concept which therefore can be caused by pain but can also have a variety of other underlying causes such as fear or hallucinations which are not necessarily symptoms of pain. However, it is also important to note that although the Discomfort Scale-Dementia of the Alzheimer's Type (DS-DAT) (Miller et al., 1996), and as Discomfort Behaviour Scale (DBS) (Stevenson, Brown, Dahl, Ward, & Brown, 2006) suggest discomfort in the name, the tools have been revised to focus on pain, and incorporate some of the AGS' suggested pain domains into the scoring system.

Additionally, it is also worth mentioning the Face, Legs, Activity, Cry and Consolability (FLACC) (Merkel, Volpel-Lewis, Shayevitz, & Malviya, 1997) scale. Although it has been evaluated for reliability and validity for clinical application with cognitively impaired people (Baiardi et al., 2002), this tool was originally designed and its primary focus is still for assessing pain in children and therefore has not been included in this section.

Lastly, a tool developed by Tsai et al. (2008) called Pain Behaviours for Osteoarthritis Instrument for Cognitively Impaired Elders (PBOICIE) has been developed to assess osteoarthritic (OA) knee or hip pain in the cognitively impaired population. This tool has demonstrated its ability to discriminate between pain behaviours before and after the administration of analgesics (Tsai et al., 2008). However, some concerns were raised regarding the sample size used for validation and correlations. Only eight participants were recruited for the validation study, which demonstrated a very low correlation for verbal self-report of pain. Moreover, it only includes two out of six of the AGS Persistent Pain Guidelines: facial expression and body movement. Due to this, the PBOICIE will not be included or discussed further in this review, as it heavily focuses on scoring pain items for individuals with a specific diagnosis of OA, rather than pain overall.

Table 2.2. Commonly used observational pain assessment tools, with number of AGS recommendation domains included and scoring information.

Name of the tool	Developers	AGS Persistent Pain Domains	Scoring
Abbey Pain Scale	(Abbey et al., 2004)	Facial expression Vocalisation Body movements Changes in interpersonal interactions Changes in activity patterns or routines Mental Status change	Each domain has a four-point scale for severity (Absent 0; Mild 1; Moderate 2; Severe 3). The total score is interpreted as follows: No pain 0-2; mild pain 3-7; moderate pain 8-13; severe pain 14+
Assessment of Discomfort in Dementia (ADD)	(Kovach, Noonan, Griffie, Muchka, & Weissman, 2002)	Facial expression Vocalisation Body movements Changes in interpersonal interactions Changes in activity patterns or routines Mental Status change	The assessor is asked to circle any domains that apply to the patient (e.g. mood: irritability, confusion, withdrawal, agitation, aggressiveness). The ADD protocol then asks the assessor to follow 5 steps to further assess: 1) physical signs of symptoms 2) current/past pain history 3) if steps 1 and 2 are negative assess environmental

			press, pacing of activity/stimulation, meaningful human interaction and intervene with non-pharmacological treatment 4) if unsuccessful, medicate with non-narcotic analgesic per written order 5) if symptoms persist, consult with physical/other health professional or medicate with PRN psychotropic per written order.
Certified Nurse Assistant Pain Assessment Tool (CPAT)	(Cervo et al., 2007)	Facial expression Vocalisation Body movements	The tool consists of 41 items in 5 major categories Facial expression (9 items) Behaviour (8 items) Mood (6 items) Body language (9 items) Activity level (9 items)
Checklist of Nonverbal Pain Indicators (CNPI)	(Feldt, 2000)	Facial expression Vocalisation Body language	Each of the following 6 items is scored on a dichotomous two-point scale: Nonverbal vocalisations Facial grimacing or wincing Bracing

			Restlessness Vocal complaints (0 = not present; 1 = present). The points are then added together. Pain is measured at rest and on movement with separate scores for each situation.
Discomfort Behaviour Scale (DBS)	(Stevenson et al., 2006)	The tool includes at least one cue from each of the 6 categories of non-verbal pain behaviours in the AGS Persistent Pain Guidelines: Facial expression Vocalisation Body movements Changes in interpersonal interactions Changes in activity patterns or routines Mental Status change	1) Grimacing, frowning, blinking, tightly closed or widely open eyes, frightened, weepy, worried, sad 2) Irritability, confusion, withdrawal, agitation, aggressiveness 3) Tense, wringing hands, clenched fists, restless, rubbing/holding body part, hyper or hypoactive, guarding body part, noisy breathing 4) Moaning, mumbling, chanting, grunting, whining, calling out, screaming, crying, verbally

			aggressive 5) Change in appetite, sleep, mobility, gait, function, participation, exiting, wandering, elopement, physically aggressive, socially inappropriate or disruptive, resists carers
Discomfort Scale-Dementia of the Alzheimer's Type (DS-DAT)	(Miller et al., 1996)	Facial expression Verbalisation Body language	Each of the below items is measured for presence or absence of indication of discomfort; those present are scored for frequency, duration and intensity: Noisy breathing Negative vocalization Content of facial expression Sad facial expression Frightened facial expression Frown Relaxed body language Tense body language Fidgeting

Doloplus 2	(Lefebvre-Chapiro, 2001)	Facial expression Vocalisation Body movements Changes in interpersonal interactions Changes in activity patterns or routines	The tool includes three subscales: Somatic reactions (somatic complaints, protective body postures adopted at rest, protection of sore areas, expression, sleep pattern) Psychomotor reactions (washing and/or dressing, mobility) Psychosocial reactions (communication, social life, behavioural problems) Each of the behavioural items includes four descriptions of behaviours rated on a four-point scale from 0 to 3 representing increasing severity of pain. Individual item scores are summed to arrive at a total score, which ranges from 0 to 30 points. Five points are the threshold stated as indicating pain.
Elderly Pain Caring	(Morello, Jean, Alix, Sellin-Peres,	Facial expression Vocalisation	The tool has 2 subscales with 8 items each

Assessment 2 (EPCA-2)	& Fermanian, 2007)	Body movements Changes in interpersonal interactions Changes in activity patterns or routines	1) Rate after 5 minutes of observation before caregiving: (a) facial expression (b) spontaneous posture adopted at rest (trying to find a comfortable position) (c) movements of the patient out of bed and /or in bed (d) interactions of all kinds with other people. 2) signs during caregiving to be rated immediately after caregiving: (a) anxious anticipation of caregiver intervention (b) reactions during caregiver intervention (c) reactions of the patient when painful parts of the body are nursed (d) complaints voiced in the course of caregiving. Each item intensity is scored on a 5-point scale, from 0 (no pain) to 4 (intense pain). The total score is the sum of corresponding scores from both subscales.
Mobilization-Observation-Behaviour-Intensity-Dementia Pain Scale	(Husebo et al., 2007) (Husebo, Strand, Moe-Nilssen,	Facial expression Vocalisation Body movements (labelled as defence)	The assessor is instructed to gently guide 1. to open both hands, one hand at a time 2. to stretch both arms towards the head, one arm at a time 3. to stretch and bend both knees and hips, one leg at a time

(MOBID and MOBID-2)	Husebo, & Ljunggren, 2010)		4. to turn in bed to both sides 5. to sit at the bedside For each activity the presence and intensity of pain is observed on an 11-point Numeric Rating Scale (NRS) for the following three behaviours: 1. Pain noises defined (e.g. Ouch!, groaning, gasping or screaming) 2. Facial expression defined (e.g. grimacing, frowning, tightening mouth or closing eyes). 3. Defence, (e.g. defined as freezing, guarding, pushing or crouching). Lastly, the assessor is asked to assign an overall pain intensity rating on an 11-point NRS.
Nursing Assistant-Administered Instrument to Assess Pain in Demented	(Snow et al., 2004)	Facial expression Vocalisation Body movements/language	The tool is divided into four sections: In section one, questions are asked about the caregiving situation (what tasks were performed and

Individuals (NOPPAIN)

whether pain was observed). Two simple questions allow the patient to self-report about pain and hurt.

In section two, the assessor is presented with 6 pain behaviours with graphic illustrations (pain words, pain noises, pain faces, rubbing, bracing, restlessness). For each of the items the assessor is asked 1) if the behaviour was observed (yes/no) and 2) to rate the intensity of the particular behaviour on a 5 point numeric rating scale (NSR) where 0= lowest intensity and 5= highest intensity.

In the third section, the assessor marks the location of pain on a body schematic.

In the final section, the assessor is asked to rate the patient's global pain intensity on that day on a verbal descriptor scale (VDS) in the shape of a pain thermometer with 6 verbal pain descriptors from "no pain" to "pain is almost unbearable."

Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)	(Fuchs-Lacelle & Hadjistavropoulos, 2004)	Facial expression Vocalisation Body movements Changes in interpersonal interactions Changes in activity patterns or routines Mental Status change	Four subscales with a total of 60 items: Facial expression (13 items) Activity/body movements (20 items) Social/personality/mood (12 items) Physiological indicators/Eating and sleeping changes/Vocal behaviours (15 items) Each item is scored on a dichotomous scale by checking off those pain behaviours that are observed. The number of checks on each subscale are added together and recorded and then these sums are added together for a total score.
Pain Assessment for the Dementing Elderly (PADE)	(Villanueva, Smith, Erickson, Lee, & Singer, 2003)	Facial Expression Verbalisation Body Movement Changes in Activity Patterns or Routines Interpersonal Interactions	Three parts with a total of 24 items Part 1 (Physical): Observable facial expression Breathing pattern Posture

			Part 2 (Global assessment): Proxy evaluation of pain intensity Part 3 (Activities of Daily Living): Dressing Feeding oneself Transfer from wheelchair to bed
Pain Assessment in Advanced Dementia (PAINAD)	(Warden, Hurley, & Volicer, 2003)	Facial Expression Verbalisation Body Movement/language	Each item is scored on a three-point scale for severity, using behavioural descriptors: Breathing Negative vocalization Facial expression Body language Consolability
Pain Assessment in Noncommunicative	(Jiska Cohen-Mansfield, 2006)	Facial Expression Verbalisation Body Movement	A total of 45 behaviours categorised according to 4 general types:

Elderly Persons (PAINE)		Changes in Activity Patterns or Routines	1. Specific repetitive behaviours: squinting, rocking, rubbing, or holding an affected area of pain 2. Specific vocal repetitive behaviours: moaning, crying, or screaming 3. Visual cues: discolouration or swollen joints 4. Change from normal behaviour: decreased appetite, difficulty chewing, wincing, increase in pacing, or unusual quietness
PainChek®	(Atee, Hoti, & Hughes, 2018)	The Face The Voice The Movement The Behaviour The Activity The Body	PainChek® consists of 42 items divided into 6 domains: The Face (9 items) The Voice (9 items) The Movement (7 items) The Behaviour (7 items) The Activity(4 items) The Body (6 items) Scores are added up and a score of 0-6 indicates no pain; 7-11 mild pain; 12-15 moderate pain and 16-42 severe pain

This literature review also revealed that the majority of the observational pain or discomfort assessment tools outlined in Table 2.2 have been tested for at least one of the following; clinical utility, internal consistency, interrater reliability, test-retest reliability, concurrent validity. Validity and reliability are discussed in more detail in Chapter 4.

The Abbey Pain Scale is classed as one of the higher standards for observational pain assessment tools. This tool has been translated into many languages including Japanese (Takai et al., 2010), Danish (Gregersen, Melin, Nygaard, Nielsen, & Beedholm-Ebsen, 2016) and Spanish (Chamorro & Puche, 2013). Moderate construct validity, adequate levels of internal consistency but low inter-rater reliability scores were found (Abbey et al., 2004).

The ADD was designed to recognise and enable facilitation of treatment of discomfort and pain among people with dementia. This tool has demonstrated high inter-rater reliability (Kovach et al., 1999), however other measures of validity and reliability such as internal consistency, criterion validity, construct validity feasibility or test-retest reliability were not reported.

The CPAT utilises three out of the recommended six AGS pain domains. The preliminary validation study has measured for inter-rater reliability, test-retest reliability, construct validity and criterion validity. The developers of the CPAT developed training for assessors, which was modified to improve overall reliability, and specifically, increase inter-rater and test-retest reliability. Following the modification of training, the study has found acceptable levels of inter-rater reliability and test-retest reliability, and acceptable internal consistency.

A sample of hospitalised patients with a hip fracture was recruited to conduct a correlational study between the CNPI and Verbal Descriptive Scale (VDS) in the original study conducted by Feldt (2000). The study found a low but significant correlation during movement, but not during rest. The results of the study also demonstrated moderate levels of internal consistency and good inter-rater reliability. However, psychometric qualities were also reported, indicating that further validity and reliability studies need to be conducted to investigate this further.

The DBS was developed and based on Minimum Data Set (MDS) which is a 250-item tool which addresses demographic, clinical and functional elements to provide an overall comprehensive assessment of residents in long-term care facilities. Only the items which were associated with discomfort were used to construct the DBS. Upon validation, the DBS has demonstrated an acceptable composite reliability

The DS-DAT was originally developed for research purposes to measure discomfort in individuals with advanced dementia who are no longer able to communicate (Warden et al., 2003). The original validation of this tool included three studies, which were conducted with dementia residents across three veteran facilities, nine long-term care facilities and two hospitals. The original study demonstrated a good correlation coefficient.

The Doloplus 2 was originally developed for young children under the name Douleur Enfant Gustave Roussy (DEGR) and has been adapted for use in older people. Lefebvre-Chapiro (2001) reported a significant convergent validity between Doloplus 2 and the Visual Analogue Scale (VAS). Furthermore, a significant result was found for an inter-rater correlation and a good level of internal consistency between two assessors.

The EPCA-2 is an 8-item observational pain assessment scale, which focuses on assessing behavioural changes in the older population (Morello et al., 2007). The first version of this scale was developed based on a literature review and a survey with experienced nurses and caregivers. This version was then refined and finalised into EPCA-2. The final version of this tool has demonstrated satisfactory discriminant and divergent validity, very good inter-rater reliability and a highly satisfactory internal consistency.

The MOBID 2 is an extended version of the original MOBID instrument (Husebo et al., 2010). The extended version of the original pain scale; the MOBID-2 has found moderate to excellent agreement for behaviours and pain, with very good inter-rater and test-retest reliability for pain intensity and a highly satisfactory internal consistency. Construct and concurrent validity have been found to be good.

The preliminary study conducted by Snow et al. (2004) for NOPPAIN was conducted with 21 nursing assistants who were asked to use the tool to assess the pain of a person who had been video recorded. The recording was played to all nursing assistants, to ensure consistency of pain behaviours throughout the study. In this study, the researchers found excellent agreement between the nursing assistants, therefore demonstrating preliminary evidence for construct validity. No other elements of feasibility, validity or reliability have been tested.

The PACSLAC developed by Fuchs-Lacelle & Hadjistavropoulos (2004) has demonstrated good content validity. This tool includes an extensive item collection, which is largely characteristic of pain in people with dementia. The developers of the PASCLAS have worked closely with nurses and professional long-term caregivers of older adults to refine the items included in this observational pain assessment tool. The preliminary validation study by Fuchs-Lacelle & Hadjistavropoulos (2004) demonstrated high levels of internal consistency, and ability to discriminate between painful, distressing and calm events; however, the correlations between global intensity ratings and the PACSLAC were moderate.

The PADE focuses on observational pain assessment tool for people with advanced dementia (Villanueva et al., 2003). After a literature review, interviews with nursing staff and observation, this tool was tested in residential care homes with 65 participants. This study reported adequate inter-rater reliability; test-retest reliability was acceptable, but low for intra-class reliability. Although the developers suggest that the scale takes 5-10 minutes to complete, this scale has been somewhat criticised for its complexity and the length of time it takes to complete (Zwakhalen, Hamers, Huijer Abu-Saad, & Berger, 2006).

The PAINAD was also developed to assess pain in people with advanced dementia (Warden et al., 2003). Unlike the PADE, the PAINAD only contains a limited number of items. This tool has demonstrated moderate internal consistency, high levels of inter-rater reliability and construct validity. The tool also correlated well with the VAS and the DS-DAT for discomfort and pain.

The PAINE was preliminarily validated across two studies, both of which recruited

residents from nursing homes as participants (Cohen-Mansfield, 2006). Internal consistency, interrater and test-retest reliability were assessed in the first study, whereas correlational validity was assessed in the second study. The PAINE demonstrated adequate internal consistency, test-retest reliability, interrater reliability and reasonable correlations against other existing measures of observational pain assessment tools.

The PainChek®, previously known as Electronic Pain Assessment Technology (ePAT), has been validated in Australia and has demonstrated excellent concurrent validity, intraclass correlation coefficient and inter-rater agreement, with good discriminant validity and predictive validity (Atee, Hoti, & Hughes, 2018). This tool uses an automated facial recognition for a more accurate assessment of facial features domain, however so far it has only been tested and validated in Australia. The author of this thesis will focus on further validation of this electronic pain assessment tool in the UK, to ensure high standard and accuracy regardless of culture, dynamics or setting globally.

The overview of validity, reliability and feasibility of the observational pain assessment tools above is a cause for some concern. While many of these tools are widely available and used by assessors, nurses and nursing home staff on a daily basis, none of them have demonstrated a strong validity, reliability and feasibility. While some have demonstrated very good to excellent internal consistency and test-retest reliability, they often lacked strong levels of correlation, inter-rater reliability and intra-class reliability. Some tools were criticised for being less feasible than others, due to a requirement of a lengthy observation prior to pain assessment. Zwakhalen et al. (2006) conducted a systematic review in which the majority of the above pain assessment tools were reviewed and assessed for quality. Each tool was scored on a scale of 0-20, evaluating psychometric properties of each scale, which included an in-depth investigation of each tool. Zwakhalen et al. (2006), scored tools based on origin of items, number of participants used for preliminary study or validation of the tool, validity (content, criterion and construct), homogeneity, reliability (inter-rater, intra-rater and test-retest) and feasibility. Zwakhalen et al. (2006) stated that PAINAD (Warden et al., 2003), PACSLAC (Hadjistavropoulos et al., 2001), DOLOPLUS2 (Wary et al., 1999) and ECPA (Jean et al., 1998) have shown the best psychometric qualities.

These four pain assessment tools all scored 11, which was the highest awarded score for the observationla pain assessment tools out of possible 20 points. The lowest scoring tools were; Pain Assessment Tool for Use with Cognitive Imapired Adults (Davies et al., 2004), The Observational Behaviour Tool and L'échelle Comportementa le simplifiée (l'ECS) (Le Quintrec et al., 1995), scoring just 4 points. The Abbey Pain Scale scored 10 out of 20 points.

It is also interesting to note that as part of the preliminary study of validation, some developers of these pain assessment tools have conducted multiple studies. The goal behind this was to see whether better training would result in stronger and more significant reliability and validity. As outlined above, tools such as CPAT have demonstrated that appropriate training can result in higher reliability and validity of an observational pain assessment tool.

2.4.2 Pain assessment training, education and knowledge

Insufficient training has been identified as a barrier to pain assessment in people with dementia (Mcauliffe, Nay, O ’Donnell, & Fetherstonhaugh, 2008), therefore provision of training is crucial for correct pain assessment. Research by Allcock, McGarry, & Elkan (2002) demonstrated that only 44% of nursing homes which used observational pain assessment tools provided training or education in pain management to their qualified nursing staff, and only 34% of nursing homes provided such training or education to healthcare assistants. Further to this, 40% of qualified nurses and 86% of healthcare assistants were lacking specialist knowledge regarding pain assessment and management. While there are some surveys designed to assess the level of knowledge, these are mostly used for research purposes. For example, the Pain in Older Adults Knowledge Survey (POAKS) (Fetherstonhaugh, Lewis, McAuliffe, & Bauer, 2016) is a 24-item survey, which presents an individual with 24 statements which are answered on a “true”, “false” or “don’t know” basis. The 24 statements are then scored, where each correctly answered statement scores as one point. The more points individuals score, the better their knowledge is. Similar scale has been developed by Zwakhalen, Hamers, Peijnenburg, & Berger (2007) as part of a study

which investigated knowledge and belief about pain in residents with dementia in the nursing home. Zwkahalen et al (2007) also reported that care home staff had deficits about several pain aspects, including pain management and treatment.

The lack of training, education and knowledge regarding observational pain assessment tools, pain recognition, assessment and management is likely to have a direct effect on the increasing prevalence of pain in people with dementia in nursing and care homes. This, therefore, suggests that there is a need to provide further education and support to qualified nurses and healthcare professionals working in nursing and care homes, to enable development of pain recognition, assessment, treatment and management for people living with dementia in nursing and care homes.

Training needs vary from tool to tool. Some tools such as the DS-DAT require extensive training due to their complexity, compared to approximately 1 hour of training required for the NOPPAIN. Not all tools have outlined their training programmes, and therefore it is difficult to evaluate the length and intensity of education and training provided for assessors overall. With research reporting that assessors and nurses in care homes find it difficult to determine whether an individual with dementia is experiencing pain and the intensity of the pain (Monroe, Parish, & Mion, 2015), it is clear that thorough and compulsory training should be provided with every observational pain assessment tool. Lack of pain behaviours in dementia training and consequently poor pain recognition and assessment may lead to poor pain management, which in turn may lead to lower quality of life (Rostad et al., 2017) and even premature death (Ibrahim, Murphy, Bugeja, & Ranson, 2015). However, it is also important to note that while training, education and knowledge are important factors in accurate pain treatment and management, there are other complex issues surrounding the use of observational pain assessment tools, including the burden of paperwork and documentation needed to be completed by care staff (Warmington et al., 2014).

2.5 Under-recognised, underestimated and undertreated pain

Researchers in the past have argued that access to appropriate pain treatment is a fundamental human right (Somerville, 2001). The failure to treat and manage pain appropriately has been viewed as unethical practice (Brennan, Carr, & Cousins, 2007), but only in 2019 the United Nations and regional human rights bodies have accepted and subsequently incorporated pain management as a key human right (Brennan, Lohman, & Gwyther, 2019). Thus, inappropriate pain recognition, treatment and management in any individual, including people living with dementia, is classed as breaching human rights. Unfortunately, as evidenced by literature outline below, pain in people with dementia is still under-recognised, underestimated and undertreated. Hence, it is crucial that research focuses on developing and implementing interventions to enhance a more accurate pain assessment, treatment and management.

There are pharmacological treatments (e.g. medication) and non-pharmacological treatment (e.g. psychosocial) strategies available for people living with dementia. The non-pharmacological treatment strategies typically include physical pain relief approaches such as repositioning to increase comfort and prevent skin pressure, massage, light physical activity (Herr, 2002) or approaches such as occupational therapy, acupuncture and social support (Podichetty & Mazanec, 2003). Other non-pharmacological approaches to chronic pain incudes Acceptance and Commitment Therapy (ACT) (Hayes et al., 1999), which is a combination of methods including acceptance, mindfulness and behaviour change methods. Improvements in mental health and functioning were in adults ages 65 years and over, who implemented ACT as treatment for chronic pain (Scott et al., 2017). These results were also supported in a systematic review which indicated that ACT is an effective treatment for chronic pain (Hann & McCracken, 2014). However, while ACT seems promising and particularly shows positive outcomes for physical and emotional functioning, this type of treatment may not be possible to implement for people living with moderate-to-severe dementia, particularly those with higher levels of cognitive impairment due to the nature of the condition.

The pharmacological strategy to treat pain is, however, the most common approach

to treat and manage pain (Horgas & Elliott, 2004). Pain is usually treated and managed with painkillers, most commonly with Paracetamol. NSAIDs or opioids are also used but only very rarely due to their side effects (Bullock et al., 2019). These painkillers are typically used to manage pain caused by a variety of comorbidities, including cancer pain, pain due to arthritis or osteoarthritis, fractures, headaches, back pain or other musculoskeletal pain, and other unclassified pain. To detect presence of pain in people living with dementia, assessors often rely on observational pain assessment tools to determine whether pain is present, and if so, how severe it is.

However, despite a wide range of observational pain assessment tools being available, research continues to consistently demonstrate misinterpretation, under-detection and mistreatment of pain in individuals with a diagnosis of dementia (Peisah et al., 2014; Seitz et al., 2014). Hendriks et al. (2014) conducted research into end-of-life stage in individuals with dementia and found that in their last week of life the most described symptom was pain, which was reported by 52% of individuals with dementia. This was followed by agitation (35%) which is thought to be a direct result of experienced pain, and lastly shortness of breath (35%).

The assessment of pain in older adults can very often be challenging due to the ever-changing and progressive symptoms and deterioration of cognitive abilities. In the past, studies have reported poor treatment and management of pain in the population living with dementia. For example, Cunningham, McClean, & Kelly (2010) have stated that pain in people with dementia is still under-recognised, which therefore likely resulted in poor treatment and management. This was also found by another study which focused on staff awareness of analgesic treatment and the consequential recognition, assessment, treatment and management of pain (Lövheim, Sandman, Kallin, Karlsson & Gustafson, 2006). In this study, 28% of residents who were identified as having pain were not prescribed any analgesics to help them manage and treat it. Further to this, Lövheim et al. (2006) have also reported that out of ten older people, six suffered from pain, of which at least one in four was not receiving any regular medication for their pain.

Nurses often attribute a change in behaviour to a psychological or psychiatric problem rather than looking for another cause (Cohen-Mansfield & Creedon, 2002; Kovach,

Griffie, Muchka, Noonan, & Weissman, 2000). Kovach, Griffie, Muchka, Noonan, & Weissman (2000) found that analgesics were often only administered after treatment with psychotropic drugs had been unsuccessful. Registered Nurses were found by Cohen-Mansfield & Creedon (2002) to focus unduly on the diagnoses stated on a person's chart as an explanation for their behaviour, rather than looking for other possible reasons. Kaasalainen (2007) reported that residents' behaviours were mostly considered to be indicative of something other than pain, with pain often investigated and assessed as a last resort in residents with dementia.

However, pain in individuals with cognitive impairment is often poorly recognised (Cunningham et al., 2010), despite training provided by some pain assessment tool developers and staff's familiarity of pain behaviour changes in individuals with dementia. One of the potential reasons for poor pain recognition and assessment is bias and subjectivity on the part of the assessor. Previous studies have demonstrated general bias and underestimation of pain by assessors (Prkachin, Solomon, & Ross, 2007). Bias can be affected by different factors, such as the race of the person being assessed, demonstrating more empathy and higher pain prescription rates for white patients (Kaseweter, Drwecki, & Prkachin, 2012), likeability of the individual (De Ruddere et al., 2011), reporting habits of individuals with dementia, acceptance of pain reports by staff, and the ability of carers to identify pain (Cook, Niven, & Downs, 1999).

The issue of undertreated pain extends outside of care home settings. Morrison & Siu (2000) conducted a study with cognitive and non-cognitive deficient patients who had undergone hip surgery and investigated pain management pre-operatively and post-operatively. The concerning findings were that cognitively intact patients received on average triple the amount of analgesics compared to patients with advanced dementia. This difference was particularly of concern given that at least 40% of the cognitively intact patients had reported very severe pain postoperatively. This demonstrated the high level of pain following a hip surgery, which was undertreated in the dementia population. Additionally, patients with dementia or other cognitive impairment were less likely to be admitted to rehabilitation facilities after hip surgery compared to cognitively intact patients (Seitz et al., 2014).

However, contrary to the studies outlined above, Haasum, Fastbom, Fratiglioni, Kåreholt & Johnell (2011) compared dementia population to non-dementia population in residential nursing homes and found that 46% of residents with diagnosis were given an analgesic daily, compared to only 25% of residents without dementia, which would suggest over-treatment as opposed to under-treatment.

Regardless of some contradictory studies, most studies seem to suggest that people with dementia are often undertreated for their pain. The inadequate management of pain in individuals living with dementia can be explained by a variety of factors; however, these factors do not excuse the poor pain treatment and management of cognitively impaired individuals. One of the factors suggests that due to a large number of comorbidities and the inability to communicate pain, clinicians can often be uncertain of the dosage of analgesic medication individuals with dementia need to be prescribed (McLachlan et al., 2010). This could be because the understanding of pain is limited due to lack of communication and feedback in those with moderate to severe cognitive impairment. The ideal treatment for these individuals is therefore predominantly experience based, but clinicians are pressured to make the right clinical decision regarding the dosage and type of analgesia without clear knowledge of the impact of cognitive comorbidities and other factors influencing pain in these individuals. However, inexperience and uncertainty should not have such a major impact on the differences of administration of pain medication in cognitively impaired individuals compared to those who are not cognitively impaired, as mistreatment and mismanagement of pain can lead to decreased quality of life.

In conclusion, this literature review has demonstrated that although there are many observational pain assessment tools available for recognition of pain in individuals with moderate to severe dementia, we are still facing a major and concerning issue where pain is under-detected and often left untreated in this population. This review has enabled to build a foundation of knowledge and understanding, and has reiterated the importance and need for a development of a better, more accurate and reliable pain assessment tool, with fewer opportunities for human error, higher rates of reliable and accurate pain assessments and therefore higher rates of appropriate treatment and increased quality of life.

2.6 Rationale

Although a wide range of pain assessment tools are available to be used by assessors across all settings including hospitals and nursing care homes, there are still major issues not just with treating and managing pain in people with dementia appropriately and effectively, but also with recognising and assessing it. The following aim has been developed as a result of this extensive and thorough literature search and review:

To examine and compare the psychometric properties of observational pain assessment tools for people living with moderate-to-severe dementia in care homes. To achieve this, four objectives were set:

a) The first objective of this study is to conduct a systematic review to further investigate the current state of observational pain assessment tools, which are available, and their psychometric properties in terms of accuracy, validity and reliability. It is hoped that the results and analysis of the pain assessment tools included in the systematic review will provide the researcher with a further insight into not only the psychometric properties of these tools, but also how they are used to help recognise, assess and treat pain. The results from this study will then be used to understand the strengths and limitations of the pain assessment tools.

b) The second objective is to conduct interviews with staff of nursing care homes, to explore views and opinions on current observational pain assessment tools, as well as PainChek®, a new electronic pain assessment tool developed at Curtin University, Australia. From the literature outlined above it was clear that although some studies did include care home staff as part of the development and validation of pain assessment tools, there is a lack of studies conducting qualitative studies into this aspect of dementia. Conducting a study qualitatively with care home staff can offer a different perspective and insight into pain detection and assessment for people with dementia in this setting.

c) The third objective is to further validate PainChek® in UK care homes. Although PainChek® has already been validated in Australia and has shown excellent

correlational reliability, it is crucial to further validate this tool in the UK where the dynamics of a care home are very different from those in Australia. Only with further validation and further demonstration of high validity, accuracy and reliability can this tool be used globally for the dementia population. Further to this, PainChek® in the UK will be tested using iOS, an operating system which has not been used for validation previously.

d) Lastly, the final objective of this thesis is to introduce three case studies of individuals living with dementia who demonstrated atypical pain behaviours and discuss what implications this might have on accurate observational pain assessment.

3 Chapter Three - Methodology

3.1 Introduction

This thesis comprises of four studies that were designed to collectively investigate and contribute toward the current knowledge of observational pain assessment tools for people with moderate to advanced dementia. Originally, in the development stages of this PhD thesis, only three studies were designed; the systematic review, the qualitative study and the quantitative study. The fourth study; the case studies; were discussed and developed during the data collection stage of the quantitative study. The case studies were included because they have offered further insight into the barriers and issues of current observational pain assessment and are important for implementation for practice and science perspective. The case study chapter offers a detailed explanation of each of the three case studies included, with a potential solution plan which can be implemented to ensure accurate and appropriate pain assessment, treatment and management.

The mixed-methods PhD thesis can therefore be considered systematic and pragmatic. The mixed methodology takes on several approaches to explore and investigate a specific phenomenon, in this case pain assessment in people with dementia, which created a holistic understanding of this psychological field, in terms of conducting research which utilises four different methodologies, all of which were underpinned by scientific evidence and theory. Glasgow (2013) provides examples of pragmatic methods, measures and models and discusses how they are applied. For example, the focus of the pragmatic approach is broken down into four components; the approach, models and frameworks, design and measures the main purpose and key factors. The purpose of the pragmatic approach should be to address a specific research question, with the models and framework being fairly simple with the attention on key issues (Glasgow, 2013). The design of a pragmatic approach should address current issues, with the purpose of measures used is to be feasible and actionable in real-world settings. When combined, the four research elements of this PhD project address a specific question in terms of pain assessment in people with

dementia and focus on application of the research findings to the current issues of assessment, treatment and management of pain in a specific population.

3.2 Pain in People with Dementia: A Systematic Review of the Psychometric Properties of Observational Pain Assessment Tools

Following the review of the literature (Chapter 2), a systematic review was conducted after some observational pain assessment tool limitations, such as human error and bias, were identified. The limitations included under-recognition, underestimation and under-treatment of pain in a dementia population. Additionally, assessor subjectivity was another identified limitation, which hindered the accuracy of identification and assessment of presence and severity of pain in people with dementia.

This systematic review has also been registered with the International Prospective Register of Systematic Reviews (PROSPERO) (see appendix 4.1).

3.2.1 Overview

As previously stated in Chapter 2, dementia in terms of prevalence, is a rapidly growing neurocognitive condition, currently affecting over 50 million individuals globally (World Health Organisation, 2019). At least 50% of these individuals experience chronic or acute pain on a daily basis (Achterberg et al., 2013). Clinicians, nurses, informal and formal care home workers often rely on self-reported subjective accounts of pain from individuals with dementia. However, once the symptoms of dementia advance, individuals often lose the ability to communicate and consequently the ability to self-report their pain. When this occurs, observational pain assessment tools are administered to help identify pain. There are approximately 30 observational pain assessment tools currently available for use by clinicians and practitioners, including

The Pain Assessment for the Dementing Elderly Scale (Villanueva et al., 2003), Pain Assessment in Advanced Dementia (Lane et al., 2003), The Non-Communicative Patient's Pain Assessment Instrument (Snow et al., 2004) and many others.

While there are many observational pain assessment tools available for use, there generally is not a single recommendation for which tool should be used universally. Because of this, further research to investigate psychometric properties in terms of accuracy, reliability and validity of observational pain assessment tools is needed. In addition, it is also important to explore why regardless of the wide range of tools available, pain in people with dementia is still majorly misinterpreted, under-detected and mistreated (Peisah et al., 2014).

3.2.2 Aims and objectives

The aim of the systematic review was to examine the reported psychometric properties of observational pain assessment tools, and where available, the influence of the obtained score on the management of pain.

The objectives were:

a) To systematically search appropriate databases to gather articles relating to pain assessment in people with dementia
b) To evaluate the overall psychometric properties of available observational pain assessment tools, in terms of concurrent validity, interrater agreement, intraclass reliability and internal consistency
c) To discuss papers which indicate a positive health outcome of observational pain assessment tools in relation to positive health outcomes and cognitive decline, where available.

3.2.3 Analytic strategy

Several processes were followed when conducting this systematic review. For example, establishing research aim and objectives helped the development of inclusion and exclusion criteria and development of a data extraction sheet. Chapter 4 outlines the systematic step-by-step process undertaken when conducting and completing the review. There were several key elements of completing the systematic review, including quality assessment and risk of bias, meta-analysis and narrative review, which all contributed to the overall findings of the systematic review.

Quality of journal articles was assessed using a 12-item checklist developed by the Critical Appraisal Skills Programme (Critical Appraisal Skills Programme (CASP), 2017). The 12 questions used were specifically designed to assess the quality of cohort studies. The questions are answered on a “yes”, “no” “can’t tell” basis, where the authors of CASP encourage the user to think about the asked questions critically. An example of a question from a cohort study CASP checklist is: “What are the implications of this study for practice?”. The CASP checklist was applied to each journal article included in the systematic review. The questions prompted the critical evaluation of each study using an established framework. In addition, a Template for Intervention Description and Replication (TIDieR) checklist was used, to evaluate each study (Hoffmann et al., 2014). TIDieR is also a 12-item checklist, which prompts the assessor to critically evaluate whether the included studies in the systematic review have identified and sufficiently explained specific aspects of interventions, in this case the interventions were observational pain assessment tools, about the materials, procedures and other elements.

Furthermore, several biases were investigated to ensure the high quality of articles included. The biases investigated included performance bias, detection bias, attrition bias and reporting bias. Performance bias (Banerjee, Pluddemann, O’Sullivan, & Nunan, 2019) in this case focuses on investigating whether there is a possibility of demand characteristics where participants or practitioners could have detected whether they were in an experimental or control group, if applicable. The detection bias focuses on whether those scoring the outcomes of the study could have been

aware of groups such as control and experimental group, and whether this could have impacted the overall results. Attrition bias (Nunan, Aronson, & Bankhead, 2018) focuses on explanation behind managing drop out in studies and reporting bias focuses on detecting evidence whether authors of articles could have omitted measures or data to present more favourable results.

The above four biases were scored on a “high risk”, “low risk” or “unclear risk” scale by two researchers independently. All stages of the systematic review were completed with another researcher, to further reduce researcher bias.

3.3 Exploring the views and opinions of care home staff on observational pain assessment tools for people with dementia: a thematic analysis

The qualitative exploratory study utilised a semi-structured, inductive approach on a semantic level using thematic analysis from constructionist epistemological stance to present and analyse data. This study recruited care home staff, including nurses, carers and visiting health professionals or GPs, to explore individual views and opinions on current observational pain assessment tools, as well as PainChek®.

A semi-structured interview method was chosen to gather information from participants regarding personal attitudes, perceptions and beliefs about observational pain assessment tools. This methodological approach is often used by healthcare professionals (Jamshed, 2014) to allow the interviewer and the interviewee to explore views and opinions about a particular topic in more depth. Due to the nature of exploratory qualitative study, semantic level of analysis was utilised to identify the explicit and surface meaning rather than utilising an in-depth analysis approach.

The qualitative study adapted and incorporated several research based and theoretical elements, including the COM-B behaviour change model (developed by Michie, van Stralen, & West, 2011), the use of the Pain in Older Adults Knowledge Survey (POAKS) (Fetherstonhaugh, Lewis, McAuliffe, & Bauer, 2016), which helped

with an in-depth understanding of personal views and opinions of observational pain assessment tools. The inclusion of the COM-B approach helped the researcher to understand how future implementation of PainChek® within care homes may be possible. The inclusion of COM-B approach will be further outlined in section 3.3.1.1.

3.3.1 Overview

When developing and validating new observational pain assessment tools, it is important to ensure that the tool is not only accurate and reliable but also feasible. Feasibility refers to the possibility to do something easily and conveniently, in terms of scoring and interpreting results from an observational pain assessment tools (Stinson, Kavanagh, Yamada, Gill, & Stevens, 2006).

Feasibility is one of the key element explored in this PhD thesis. Tools should not only be reliable but also user friendly and convenient to use by the targeted audience (i.e. observational pain assessment tools should be designed with nurses and caregivers in mind).

While some studies claim to test feasibility as well as reliability of observational pain assessment tools, the focus of the published articles seems to be on reliability and validity only rather than feasibility. For example, the study by Pautex et al. (2005) aimed to evaluate the feasibility and reliability of several pain assessment tools for people with dementia, yet feasibility is only very briefly mentioned in the abstract and the introduction and lacks focus in the results and discussion. It was unclear how feasibility was measured, what the researchers classed as feasibility and the implications of this. Pautex et al. (2005) discuss the ability to complete a pain assessment by people with dementia, which although it is interesting, it is unclear whether this was linked to feasibility of the tools. Furthermore, in a research conducted by Zwakhalen, van't Hof, & Hamers (2012), the main aims were also to investigate the feasibility of regular pain assessment using an observational pain assessment tools in a care home. This article was somewhat better in terms of introducing feasibility, but

it still relatively unclear how it was investigated. Zwakhalen et al. (2012) used structured interviews to gain an insight into feasibility and the experiences of using pain assessment tools, but detailed and further information about this is lacking.

The research outlined above provided a critical understanding, which formed part of the rationale for the qualitative study. Thus, this qualitative study utilised semi-structured interviews to explore perceived feasibility of care home staff regarding two observational pain assessment tools. The first tool, the Abbey Pain Scale, was included in the interviews for two reasons. Firstly, the Abbey Pain Scale was already used routinely within the recruited care home. This allowed the participants in the study to directly relate to their previous experiences with pain assessment during the interviews. Secondly, the Abbey Pain Scale is one of few observational pain assessment tools which has similar properties and features to PainChek®, such as utilisation of all six pain domains recommended by the AGS (AGS Panel on Persistent Pain in Older Persons, 2002). In addition to this, PainChek® has been developed based on the design of the Abbey Pain Scale, therefore similarities and comparisons are likely to be noticed by the participants. PainChek® is the second observational pain assessment tool investigated in this qualitative interview. Perceived feasibility of PainChek® was investigated to develop an understanding of practicality from potential future users.

In the semi-structured qualitative interviews, feasibility was measured in terms of perceived strengths and limitations of observational pain assessment tools, and the perceived applications to care home settings. For example, amongst other open-ended questions, participants were presented with PainChek® in a form of 2-minute video. The participants did not use the PainChek®, but they may have seen it used in practice by the researcher of this thesis during the data collection period. The participants were asked to elaborate on whether they thought PainChek® would or would not have been easy to use in a care home setting, and why.

3.3.1.1 Application of the COM-B Behaviour change model

The implications of the findings of the qualitative study are partially applied back to the COM-B Behaviour Change Model. The COM-B model was developed by Michie, van Stralen, & West, (2011) and focuses on ways to improve the design and implementation of evidence-based practice through behaviour change interventions. The COM-B model suggests that capability, opportunity and motivation are the three components which affect behaviour. The COM-B model has been used previously to develop an intervention to improve the regular and long-term use of hearing aid (Barker, Atkins, & de Lusignan, 2016). The researchers in the hearing aid study used the COM-B framework to develop qualitative structured interviews to identify how to promote hearing aid use, by designing interview questions which specifically map onto the three components; capability, opportunity and motivation. While the present qualitative study did not develop semi-structured interviews based on the COM-B approach, some of the findings can be applied to this model. The use of the COM-B model was suitable in this study, as it helped gather information about the observational pain assessment tools in terms of previous experiences with the Abbey Pain Scale and potential barriers to implementation of the PainChek®.

The partial application and discussion of the COM-B model acted as an aid to understand the best approach towards implementation of a new observational pain assessment tool within care home settings. This approach may help to understand why observational pain assessment tools have suboptimal use, and what the key perceived aspects in terms capability, opportunity, motivation and changing behaviour are to increase the frequency of accurately utilising pain assessment tools. The implementations and applicability of the COM-B model in terms of the qualitative results is further discussed in Chapter 5.

3.3.1.2 The Pain in Older Adults Knowledge Survey (POAKS)

The Pain in Older Adults Knowledge Survey (POAKS) (Fetherstonhaugh et al., 2016) is a tool developed to measure the knowledge of nursing and care home staff regarding their experience, assessment and management of pain in older people. The tool has been developed specifically for the use in care homes and residential facilities. The survey includes 24 statements which are scored on a three-point scale (true, false or don't know). The tool can be used by quality management, service providers or researchers who are interested in improving outcomes of care home facilities.

As previously stated in the literature review (Chapter 2) insufficient training, education and knowledge have been identified as one of the barriers to accurate pain assessment in dementia. Therefore, in this case, the POAKS survey was given to all participants prior to collecting qualitative data, with the aim to establish knowledge levels among care home staff and health professionals who work or regularly visit the care homes. The scores from the POAKS survey helped to form a discussion in terms of how knowledge and education of care home staff can affect the appropriate and correct use of observational pain assessment tools in care home settings. However, information about prior training or education were not recorded.

3.3.2 Aims and objectives

The aim of the qualitative study was to explore feasibility in terms of views and opinions of care home staff and allied health professionals of PainChek® and Abbey Pain Scale.

The objectives were:

a) To explore views and opinions regarding the PainChek® and the Abbey Pain Scale with care home staff and allied health professionals using semi-structured interviews

b) To investigate common themes and sub-themes regarding the feasibility of PainChek® and Abbey Pain Scale in terms of perceived strengths and limitations using a thematic analysis technique
c) To briefly explore participant level of knowledge regarding pain in the older people using the Pain in Older Adults Knowledge Survey (POAKS)

3.3.3 Epistemological stance

Epistemology is a branch of philosophy which is concerned with the theory of knowledge. The epistemological stance is adopted in an attempt to provide answers to questions which involves thinking about the nature of knowledge. The aims and objectives of qualitative research need to be clear before analysis and interpretation of the data set are presented (Willig, 2001). This can be achieved by clearly setting out and justifying the epistemological and ontological stance.

An exploratory analysis was adopted for this qualitative study, therefore it was difficult to pinpoint a single epistemological stance which underpinned the aims and analytical approach of the whole study. The qualitative aspect of this PhD thesis was truly an exploratory study, which helped to understand the opinions and views of individuals who were likely to come across or use observational pain assessment tools. The study did not aim to interpret or analyse the answers from a specific perspective it was simply designed to explore what care home staff and allied health professionals thought about current observational pain assessment tool as well as PainChek®. Thus, an in-depth interpretation of the transcripts was not needed and therefore the transcripts were analysed on a semantic level.

As the different types of epistemologies were explored, at first an empiricist epistemology was considered for adaptation in this research. Empiricism is a theory with a belief that all knowledge within individuals is built from sense experience (Markie, 2017). In other words, the only and all knowledge individuals can have, is based on prior experience. This would have applied to the present qualitative study to an extent, given that the majority of the participants interviewed have used

observational pain assessment tools on regular basis. However, this epistemology would be difficult to apply for the second phase of the qualitative interviews, which introduced the participants to PainChek®. PainChek® was a newly developed semi-automated pain assessment tool, which at the time was not available for use by any clinical or care home settings, therefore participants would not have experience of using this tool. Therefore, empiricism was not adapted. Other epistemological stances were also considered, such as critical realism, positivism or interpretivism, however, there were elements within each of these philosophical stances which did not resonate with the overall aims of the research. For example, realism is concerned with knowledge about any object being concerned independently of the mind, positivism states that only facts which derived from a scientific method can make valid claims about knowledge, and interpretivism focuses on how a researcher is part of the research, meaning that they will always interpret data subjectively.

Taking all of the above epistemological stances into consideration, constructionist epistemology seemed to be the most appropriate philosophical approach to apply to the qualitative study and its aims. Constructionism is the belief that our knowledge is constructed through convention, human perception and social experience. This stance is pragmatic and relativistic in nature, meaning that the nature of knowledge, language, phenomena, meaning, belief and science are all best viewed in terms of their practical use and success. The adoption of this stance is useful for two reasons. Firstly, it is a suitable stance for the interview participants who were able to apply their previous knowledge and experience of the Abbey Pain Scale and other observational pain assessment tools when answering interview questions. Secondly, it also directly links with the overall pragmatic approach of the whole PhD project, which focused on addressing current issues in the field of pain and dementia and finding ways to resolve them. However, it is important to note that this epistemological stance was difficult to apply to the second phase of the interviews, which focused on discussing feasibility of PainChek®. This is because participants have had no prior experience or exposure of this tool, and therefore they were unable to apply or discuss their views and opinions to the same extent as they did for the APS. As such, an exploratory and semantic approach was taken when analysing the transcript from the interviews.

3.3.4 Analytic strategy

The qualitative study utilised a semi-structured interview approach. Given the open-ended nature of this qualitative study, an inductive thematic analysis technique at a semantic level was used, to facilitate the identification of common themes from the data set. An inductive qualitative approach to data analysis refers to a process of data coding without trying to fit them into pre-existing coding frames or the researcher's analytic perception. In other words, the identified themes are strongly linked to the collected data set, not driven by theory or the researcher's theoretical interest in the topic area, making the findings are data driven. This was an important methodological approach to adapt, as it allowed the researcher to identify and categorise views and opinions on observational pain assessment tools of care home staff into themes.

The semantic approach focuses on reporting and presenting data in the way they have been collected and transcribed, rather than interpreting and investigating them beyond what the participants have said. Still, the semantic level of analysis aims to report and present identified themes or categories which progresses from a descriptive level. The themes, which have been identified, were presented and reported with an explicit surface meaning, however, the data were organised into categories and summarised, with an attempt to theorise the significance of the themes and implication of their broader meaning in terms of views and opinions of observational pain assessment tools.

Thematic analysis is a method for identifying, analysing and reporting patterns or themes within data sets (Braun & Clarke, 2006). This method of analysis was chosen due to its flexibility during analysis and interpretation of data, and the appropriateness of its use when identifying the most commonly mentioned views and opinions of observational pain assessment tools.

A following 6-phase guide was used to carry out the thematic analysis, as outlined by Braun & Clarke (2006):

1. Familiarisation

   The first phase requires the researcher to become familiar with the data set, through data immersion. Immersion refers to the manual transcription of the audio recordings, repeated reading or listening of the interview transcript or taking notes of the topics which are often talked about by the participants.

2. Generating initial codes

   The second phase focuses on assigning codes to sections of the data set. A section in the data set can have multiple codes, but it is important to note that codes are used to describe or categorise a section of a transcript, not to interpret the text.

   The generation of initial codes can be completed manually or with the help of specific coding software. In this case, to enhance the familiarisation and immersion phases, the researcher has generated initial codes manually. Once all data were coded, the codes were collated together with other sections that were given the same code.

3. Searching for themes

   In this phase, the process of sorting the codes into themes began. The researcher looked at the codes with the associated extracts and categorised them into broader themes. For example, codes labelled “time consumption” and “complexity” were combined to create the main theme labelled “limitations of observational pain assessment tools” where the codes became sub-theme of the main theme. This process was repeated several times until all codes were allocated within broader themes.

4. Reviewing themes

   In this phase, the researcher ensured that the codes which because sub-themes were suitable and appropriate for each identified main theme. This

involved reading and re-reading the extracts from each code, exploring whether the extract supported the main theme, and ensuring that the extracts across main themes or sub-themes do not overlap or contradict each other within the sub-themes. Once all the extracts within individual sub-themes were coherent, the researcher was able to continue to phase five.

5. Defining and naming themes

   The fifth phase of thematic analysis required the researcher to describe and name each identified main theme. Braun & Clarke (2006) suggest that the names for each main theme should be descriptive and engaging. Definition of each main theme should be provided, with a clear focus on not only describing the main theme but also outlining what and why the theme is interesting.

6. Producing the report

   The final phase in Braun & Clarke's (2006) 6-phase guide is the reporting of the themes and sub-themes. The report writing should include elements such as enough information about the project and processes taken to collect and analyse data. Supplementary quotes to illustrate the identified sub-themes were included, and the structure of the report was clearly set out to enhance the clarity, flow and coherence of the report.

It has been acknowledged that conducting semi-structured interviews and using thematic-analysis to develop codes is a subjective process. However, subjectivity in qualitative research is accepted by qualitative researchers, and do not undermine the research but instead are essential to a high standard of qualitative practice (Clarke & Braun, 2013). However, to reduce bias, a data-driven inductive approach was adopted where the data were analysed and coded first before applying a theoretical underpinning.

3.4 Validation and Evaluation of Psychometric Properties of PainChek®: A Semi-automated Pain Assessment Tool for People with Moderate-to-Severe Dementia in the UK

The quantitative study utilises a within subjects correlational design to further validate PainChek® through evaluation of psychometric properties. Psychometric properties refer to properties which measure validity and reliability of an instrument or a tool, where validity refers to whether the instrument measures what it has set out to measure and reliability refers to consistency (Souza, Alexandre, & Guirardello, 2017). To achieve this Abbey Pain Scale, an observational pain assessment tool was compared directly against the PainChek® during data collection. Pain scores from the PainChek® and the Abbey Pain Scale were collected from participant at rest and immediately post-movement. The data from the two conditions; at rest and post-movement, were collected to replicate comfort condition and to initiate nociceptive experience. Nociceptive type of pain is "pain that arises from actual or threatened damage to non-neural tissue and is due to the activation of nociceptors" (International Association for the Study of Pain, 2017).

The participants consisted of care home residents with a diagnosis of dementia and a secondary diagnosis of a chronic pain condition. Each participant completed a Mini-Mental State Examination (MMSE) (Folstein, Folstein, & Mchugh, 1975b) to establish the level of cognitive impairment. Pain scores from PainChek® were collected by the researcher only, whereas the pain scores from the Abbey Pain Scale were collected by a recruited nurse. Data from both observational tools were analysed for validity and reliability. However, while a wide variety of information such as level of cognitive impairment, clinical and demographic information such as diagnosis of pain condition and dementia, age, ethnic background or gender were collected, data about quality of life for individuals living with dementia were not collected. While information about quality of life should be focused on in future research, this study focused on the first step of pain observation, which is validating an observational pain assessment tool in the UK. Once this tool has been validated, further studies which focus on implementation can be conducted.

3.4.1 Overview

PainChek® has previously been validated in Australia by Atee, Hoti, & Hughes (2018). To establish validity and reliability of PainChek® universally, it was useful to implement the validation process across multiple aged care facilities and countries, to ensure consistency of accuracy across cultures. This is especially important for an instrument which introduces a new element to observational pain assessment, in this case, an automated facial recognition technology which has been trained to detect micro-facial expressions which are indicative of pain.

Both PainChek® and Abbey Pain Scale utilise all six pain domains recommended by the American Geriatrics Society (AGS Panel on Persistent Pain in Older Persons, 2002). Additionally, the American Geriatric Society (AGS) Panel on Persistent Pain In Older Persons (AGS, 2002) recommends the use of key six behavioural domains to be considered for a comprehensive pain assessment in people with moderate-to-severe dementia. The six domains consist of:

1. Facial expression (e.g. frowning, rapid blinking)
2. Verbalisation and vocalisation (e.g. moaning, groaning)
3. Body movements (e.g. guarding sore areas, pacing)
4. Changes in interpersonal interactions (e.g. withdrawn or disruptive behaviour)
5. Changes in activity patterns or routines (e.g. changes in sleep routines or change in appetite)
6. Mental status changes (e.g. crying or increased confusion).

3.4.2 Aims and objectives

The aim of the quantitative study was to further validate and evaluate the psychometric properties of the PainChek® in UK care homes, using a new operating system (Apple iOS), with a British cohort of individuals living with dementia.

The objectives were:

a) To compare the PainChek® directly against another observational pain assessment tool, in this case, the Abbey Pain Scale
b) To investigate the psychometric properties of the PainChek® by conducting an evaluation study with individuals with dementia living in a UK care home
c) To investigate whether the PainChek® continues to accurately and reliably recognise and assess pain, despite the deterioration of cognition as a result of the progression of dementia

3.4.3 Hypotheses

The quantitative validation study had the following two hypotheses:

1. There will be a strong positive significant correlation between the Abbey Pain Scale and the PainChek® pain scores (in overall pain scores, rest pain scores and post-movement scores categories).
2. The reliability tests of the PainChek® will demonstrate at least a substantial interrater agreement, moderate intraclass reliability and satisfactory internal consistency when compared against the Abbey Pain Scale.

3.4.4 Validity and reliability of materials

The materials for the quantitative study consisted of three scales; 1) the Mini-Mental State Examination developed by Folstein, Folstein, & Mchugh (1975), which has been designed to assess the level of cognitive impairment in individuals with dementia, 2) The Abbey Pain Scale (Abbey et al., 2004), which is one of the many observational pain assessment tools used to recognise and assess pain in people with dementia and 3) PainChek® (Atee, Hoti, Parsons, & Hughes, 2017b) the pain assessment tool which has been validated as part of the PhD project.

Except for the PainChek®, the Abbey Pain Scale and Mini-Mental State Examination Scale have been carefully chosen to ensure they are highly valid and reliable. Although there is not a single recommendation for an observational pain assessment tool universally, the Abbey Pain Scale is considered to be one of the standard tools for assessing pain in patients with dementia in Australia (Australian Government, Department of Health, 2018), and therefore it was deemed to be an appropriate tool to use in psychometric properties analysis against PainChek®. PainChek®, on the other hand, was chosen for further validation as during the early stages of this PhD, PainChek® was in the early stages of development and validation. To strengthen psychometric property results, the decision to validate PainChek® across countries (Australia and UK) and in care homes with cultural differences was made. Additionally, in the validation study by Atee, Hoti, & Hughes (2018), an early Android version was validated, whereas in this study a newer version using Apple iOS was validated. Lastly, Atee, Hoti & Hughes (2018) formed the initial developmental team and were therefore highly familiar with how the PainChek® functions and performs, whereas the researcher in this thesis was provided with training therefore replicating the conditions of future implementation of PainChek® in care homes.

The subsections below will explore the strengths and limitations of the Abbey Pain Scale, the PainChek® and the MMSE.

3.4.4.1 Abbey Pain Scale

The Abbey Pain Scale (APS) is an observational pain assessment tool designed for people with end-stage of dementia (Abbey et al., 2004). The APS includes six pain domains, with each domain scored on a four-point scale (0 = absence of painful behaviour, 1 = mild, 2 = moderate and 3 = severe presence of pain behaviour). The total score for APS ranges from 0-18, where scores of 0-2 indicate no pain, 3-7 mild pain, 8-3 moderate and 14 + severe presence of pain.

Like most observational pain assessment tools, the APS is designed to measure a change in behaviour in individuals, and therefore the individual who completes the assessment using APS must be familiar with the individual being assessed.

3.4.4.1.1 Limitations of the Abbey Pain Scale

As with all pain assessment tools, the APS also has some limitations. Brown (2011) suggests that one of the limitations of the APS is its lack of ability to distinguish between painful and distressing behaviour.

As mentioned above, the individual who completes the APS pain assessment must be familiar with the person being assessed. As such, it has therefore been criticised for not being a suitable tool in acute care settings such as emergency departments or hospitals (Hadjistavropoulos, Fitzgerald, & Marchildon, 2010). To mitigate against this limitation in the validation study of this PhD project, the nurse who completed all APS assessments worked in the care home for a length of 6 years at the time of data collection and was therefore familiar with all residents of the care home. Further to this, the researcher spent 5 months visiting the care home prior to data collection, to ensure familiarity with the care home routines and the resident's behaviour.

3.4.4.1.2 Strengths of the Abbey Pain Scale

While there is no recommendation for a single observational pain assessment tool to be used in the UK, the National Guidelines for the assessment of pain in older people have a practical suggestion of APS as a scale selection when assessing pain in older people with severe cognitive or communication impairments (Closs et al., 2007), which demonstrates its suitability as a tool to be compared against in validation studies.

Additionally, the APS was validated with 61 late stage dementia participants in a care home setting (Abbey et al., 2004), which further demonstrates its suitability to be used in this study, which aims to validate PainChek® in a care home setting. The APS is one of the few observational pain assessment tools which utilises all six pain domains recommended by the American Geriatrics Society (AGS, 2002).

3.4.4.2 PainChek®

The PainChek® is a semi-automated observational pain assessment tool designed to detect and assess the presence and severity of pain in people with moderate-to-severe dementia. The PainChek® is a novel smartphone application (app) tool, designed by Curtin University researchers in Australia. Due to its newness, only few studies have been published which investigated its psychometric and clinometric properties as well as strengths and limitations (Atee, Hoti, & Hughes, 2018; Atee, Hoti, Parsons, & Hughes, 2017a; Atee et al., 2017b; Atee, Hoti, Parsons & Hughes, 2018; Hoti, Atee, & Hughes, 2018).

The PainChek® utilises the following six pain domains; face, voice, movement, behaviour, activity and body, which operates on a 0-42 point scale where a score of 0-6 indicates no pain, 7-11 mild, 12-15 moderate and 16-42 severe pain.

3.4.4.2.1 Strengths of PainChek®

Based on previous validation and evaluation of psychometric properties studies, the PainChek® has so far demonstrated to be an excellent tool in terms of validity and reliability. For example, Atee et al. (2017a) demonstrated an excellent level of correlation between the Abbey Pain Scale and the PainChek® when assessing pain at rest and immediately post-movement in a cohort of residential aged care participants. Additionally, similar excellent findings were reported in a study by Atee et al. (2018) second study which focused on evaluation psychometric properties of PainChek®

(Atee, Hoti, & Hughes, 2018). The results demonstrated excellent concurrent validity and reliability measures, good discriminant validity, and predictive validity measures in addition to demonstrating excellent clinimetric properties and therefore indicating clinical utility and usefulness of PainChek® for people with moderate-to-severe dementia (Hoti et al., 2018).

However, while PainChek® is demonstrating excellent psychometric and clinimetric properties, so far it has only been validated in Australia. To demonstrate implications of this tool across cultures, the PainChek® has also been validated in the UK as part of this PhD, which was one of the first steps outside of Australia to implement PainChek® as a universal observational pain assessment tool.

3.4.4.2.2 Limitations of PainChek®

So far, the only identified limitations for PainChek® were in reference to the design of the validation studies. For example, Hoti et al. (2018) noted that the sample size was relatively small and all data were collected from an Australian aged care facility, therefore the results of this study need to be interpreted with caution. Further limitations included homogenous sample in terms of gender and ethnicity, where mostly Caucasian females were recruited and others. However, so far no limitations which were directly linked to the accuracy, validity or reliability of PainChek® have been highlighted.

3.4.4.3 Mini-Mental State Examination

The UK government has a policy titled ‘improving care for people with dementia’, which is committed to improving rates of diagnosis for individuals with dementia symptoms. As part of the policy, and until November 2014, every individual aged 65 to 74 years

of age was provided with information about dementia and referred to a cognitive assessment if required. The individuals who were referred for cognitive testing were usually assessed by one of the three following cognitive instruments; the Mini-Mental State Examination, the 6-item Cognitive Impairment Test, the General Practitioner Assessment of Cognition or the 7-Minute Screen (NICE, 2014).

However, in November 2014, the UK National Screening Committee reviewed the aforementioned guidelines regarding screening all individuals over the age of 65 and has decided to no longer provide this screening unless symptoms of dementia were present (UK National Screening Committee, 2015). One of the reasons behind this decision was that not all individuals who obtain a score of mild cognitive impairment on the scale go on to develop dementia. As such, the screening of severity of cognitive impairment was therefore only provided to those who were already showing symptoms of dementia. Regardless of this change, the participants in this study already had a formal diagnosis of dementia, and while the sections below discuss the accuracy, validity and suitability of MMSE as an instrument, it is important to keep in mind that in this study, MMSE was not used as a diagnostic tool, but instead it was used as an indicator of cognitive impairment severity in participants.

The MMSE is not recommended as a dementia diagnostic tool (Tidy & Jackson, 2016), but it is clear that this tool is one of the most frequently used instruments to identify the level of cognitive impairment by health professionals in research and clinical settings (Tsoi, Chan, Hirai, Wong, & Kwok, 2015). Additionally, in two studies conducted by (Mitchell, Psych, & Malladi, 2010a, 2010b), a single and a multi-domain dementia screening tests were assessed to investigate the accuracy of detection of cognitive impairment in individuals with dementia. Single domain tests focus on only one domain of cognitive impairment such as memory or verbal fluency, compared to multi-domain cognitive impairment tests which combine multiple domains into a single test (Mitchell et al., 2010a).

The two meta-analyses by Mitchel et al. (2010a, 2010b) compared the single and multi-domain tests directly to MMSE. The studies compared 19 brief multi-domain and 8 brief single-domain MMSE alternatives. The alternative screening tests for cognitive impairment included multi-domain instruments such as 6-item Cognitive Impairment

Test (6-CIT), Mental Status Questionnaire or the Abbreviated Mental Test Score. The single-domain tests included the selective reminding test or clock-drawing test. In both meta-analyses, the researchers acknowledged the wide variety of single and multi-domain tools available. The two key recommendations from the two studies are to 1) consider the use of single domain tests as a first step to gauge cognitive impairment in people with dementia, and 2) to use the MMSE or the 6-CIT in primary care, and either 6-CIT or an instrument called MINI-Cog in specialist care.

3.4.4.3.1 Limitations of the MMSE

Carnero-Pardo (2014) published a critical article outlining the key qualities and characteristics which an ideal cognitive impairment test, such as the MMSE, should have. The characteristics and qualities were divided into three sections; characteristics, psychometric properties and other.

The characteristics section suggested that an ideal cognitive impairment instrument needs to be short. In other words, the administration of a cognitive impairment instrument should take no longer than five minutes in a primary care setting and no longer than ten minutes in a specialist hospital care setting. Further suggestions of characteristics which should be present in a cognitive impairment instrument were that the instrument is simple and easy to use, is suitable for illiterate individuals, does not require pen and paper, is ecologically valid, acceptable, culturally adaptable, flexible, inexpensive and free of charge.

The MMSE takes seven to ten minutes to administer, and therefore is considered too lengthy for a primary care setting consultation but may be more appropriate for use in a specialist hospital setting. In a USA based study, 58% of participants who were asked about the feasibility of the MMSE stated that the administration time was too lengthy (Tangalos et al., 1996). Additionally, other multi-domain cognitive impairment screening tests such as the Rowland University Dementia Assessment Scale - RUDAS (Storey, Rowland, Conforti, & Dickson, 2004), can take over 15 minutes to

administer when diagnosing dementia in individual, therefore the MMSE can be considered a fairly short cognitive impairment instrument. Moreover, as the MMSE includes domain which focuses on writing and reading, it has been criticised for not being suitable for illiterate individuals (Blesa et al., 2001). This also extends to individuals who are unable to communicate completely, either because of the advanced stages of dementia or due to other underlying issues, which makes the MMSE near impossible to administer.

Furthermore, while the MMSE does require a pen and paper for its completion, based on the experiences of the author of this thesis, it is very simple and easy to use. Perhaps developing an electronic version would be beneficial in terms of accessibility, safer storage and easier transfer to other electronic health records, it is unlikely that a non-paper and pen-based version would increase or decrease the accuracy and reliability of the instrument any more. In addition, cultural and linguistic adaptation has been demonstrated via the translation of MMSE to at least 15 languages including Chinese (Xu et al., 2003), Finnish (Salmon et al., 1989), French (McDowell, Kristjansson, & Hébert, 1997).

The second component of the ideal qualities and characteristics outlined by Carnero-Pardo (2014) is focused on the psychometric properties of the instrument. This component focuses on validity, reliability and responsiveness of the instrument, with no ceiling or floor effect. The ceiling or floor effect occurs when a high proportion of participants in the study obtain either maximum (ceiling) or minimum (floor) scores on a scale. Ceiling effect can also occur when observational scales are skewed so that it is too easy to reach the maximum amount of points (Howe, 2018). The MMSE has been criticised for its ceiling and floor effect. The MMSE has demonstrated a high positive correlation coefficient when compared to another cognitive impairment tool, and significantly positive test-retest reliability (Pangman, Sloan, & Guse, 2000). However, studies have previously indicated the floor and ceiling effects as one of the limitations of the MMSE. Franco-Marina et al. (2010) define an MMSE floor effect as an adversely affected performance due to personal characteristics, which are independent of cognitive functioning and therefore resulting in reduction of test specificity. On the other hand, the MMSE ceiling effect has been defined as a favourably affected performance due to personal characteristics, which are

independent of cognitive functioning and therefore reducing test sensitivity. This, therefore, supports the outlined MMSE limitations by Carnero-Pardo (2014), and imply that when MMSE is used as a diagnostic tool, there is a potential that individuals may be diagnosed with dementia when dementia is not present, and vice versa.

The final component in the key qualities and characteristics to an ideal cognitive instrument falls under the 'other' section. The requirements in this section state that the cognitive instrument must have normative studies available, has been validated specifically for cognitive impairment, has been validated specifically in the setting in which it will be administered (e.g. primary care homes or specialist hospital settings), must include several cognitive domains (e.g. memory, executive function), and must suggest a clinical or diagnostic profile. While the MMSE has not originally been developed specifically for dementia, the multi-domain screening test allows the evaluation of several domains at once. A meta-analysis conducted by Mitchell (2009) investigated the accuracy of MMSE in the detection of dementia and mild cognitive impairment.

The meta-analysis indicated that the MMSE was modestly effective at ruling out dementia in individuals with moderate cognitive impairment in a dementia specialist setting such as memory clinics. However, in the same study, the findings have suggested that the MMSE was significantly better at ruling out dementia in settings, which were not dementia specialised such as primary care setting. Furthermore, the author of the meta-analysis continues to state that there is value in the MMSE in both, a specialist and non-specialist settings. In a specialist dementia setting, the MMSE was reasonably effective at identifying dementia, compared to a non-specialist setting where the MMSE was reasonably effective at ruling out dementia. In both cases, the author reiterates the importance of careful consideration of the MMSE score, and in addition, suggests that the MMSE should not be used alone as a diagnostic tool.

3.4.4.3.2 Strengths of the MMSE

Despite the above outlined limitations and recommendations for the retirement of the MMSE (Carnero-Pardo, 2014, 2015), the MMSE is still one of the most popular and widely used cognitive impairment screening tests used for research purposes. The key limitations outlined in the above section, have been challenged by Rodríguez & Pareja (2015), who address most of the limitations outlined by Carnero-Pardo (2014, 2015) as a reason to retire the MMSE. Firstly, Rodríguez & Pareja (2015) state that the arguments for the retirement of the MMSE lack scientific basis. Next, the following arguments offer a more in-depth insight into the strengths of MMSE.

Studies, which tested for psychometric properties, demonstrated that the MMSE is able to discriminate between individuals who are cognitively intact and those with cognitive deterioration due to including a multi-domain approach. Specifically, the orientation, attention and language (which included repetition and comprehension) domains, were useful domains to help differentiate between levels of cognitive impairment in individuals, in a study which investigated psychometric properties of the MMSE in a Spanish population (Prieto, Contador, Tapias-Merino, Mitchell, & Bermejo-Pareja, 2012). Furthermore, Lopez, Charter, Mostafavi, Nibut, & Smith (2005) states that despite some limitations, the MMSE has been around for over 40 years and has become very popular and is often used by health professionals due to its feasibility. However, when used as a screening test for cognitive impairment, the limitations should be carefully considered and the scores carefully interpreted.

Further to this, the role of the MMSE in this PhD project was not to diagnose participants with dementia but to gauge the presence and severity of cognitive impairment and its progress over the data collection period. All participants in the validation study have already been diagnosed with dementia and were classed as having moderate-to-severe dementia or end-of-life dementia. The MMSE has been used to help track changes of cognitive impairment over a period of time. A meta-analysis conducted in 2000, has demonstrated that at least 37 longitudinal studies have used the MMSE to track cognitive impairment in patients (Han, Cole, Bellavance, Mccusker, & Primeau, 2000), which demonstrates another use for the MMSE.

Moreover, a study by Kim et al. (2017) investigated 204 patients for an annual decline in cognition using the MMSE and a second instrument; Neuropsychological Battery. The patients were either diagnosed with Alzheimer's disease or had an amnestic mild cognitive impairment. The two cognitive impairment instruments were used to track cognitive decline over a period of time. The results have shown that while the neuropsychological battery might be a more effective tool to track decline in cognition for patients with amnestic mild cognitive impairment, the MMSE was best suited for the patients with a diagnosis of Alzheimer's disease. These results suggested the appropriateness of the use of the MMSE, as a way to track cognitive decline in people with dementia, in particular people diagnosed with Alzheimer's disease.

Another strength of the MMSE is that this multi-domain cognition-screening instrument evaluates six domains: orientation, registration, concentration and calculation, recall, language and constructional praxis.

Based on the information above, and with knowledge from previously published literature and research studies, it was therefore decided that the MMSE is an appropriate instrument to test for cognitive deterioration for the quantitative study. It is also important to note, that the MMSE was *not* used to diagnose dementia. Instead, the MMSE was used to give the author of this thesis an idea of how severe the cognitive impairment is in the participants of the quantitative study.

The MMSE was administered at the baseline (week 1) and again at the end of data collection (week 16) and compared in terms of means and standard deviation. Another important note to make is that the two MMSE scores were only obtained to investigate whether the PainChek® instrument continues to accurately and reliably recognise and assess pain, despite deterioration of cognition as a result of the progression of dementia.

3.4.5 Analytic strategy

Upon data collection completion, raw data were entered into a password protected Excel spreadsheet manually. Values per each category of each domain were entered individually, to allow for an in-depth data exploration and analysis. Data were also labelled into one of two categories (rest or post-movement) to enable a detailed analysis and comparison of correlations, reliability and validity measures across the three conditions (rest, post-movement and overall).

All statistics were analysed using IBM SPSS-26. The demographics of study participants and raw data were analysed using standard descriptive statistics, including mean, median, mode, range, standard deviation and frequencies or percentage for pain diagnoses and types of dementia.

As this was a correlational design, concurrent validity was measured using Pearson's correlation coefficient *r* value. This allowed the researcher to investigate the relationship of pain scores between pain scores gathered from PainChek® and Abbey Pain Scale. Pearson's correlation coefficient is a measure of the strength of a linear association between two variables. In this case, the two variables were pain scores indicated by the Abbey Pain Scale, and pain scores indicated by the PainChek®. Pearson's correlation coefficient was one of the statistical measures studies when investigated psychometric properties of PainChek® in UK care homes. The interpretations of Pearson's correlation coefficients are outlined in table 3.1.

Table 3.1. Strength of correlation with values as outline by (Hinkle, Wiersma, & Jurs, 2003).

Strength of correlation	Pearson's or Spearman's *r* value
Negligible correlation	.0 to .3
Low positive correlation	.3 to .5

Moderately positive correlation	.5 to .7
High positive correlation	.7 to .9
Very high positive correlation	.9 to 1

Other measures, which enabled the researcher to investigate the psychometric properties of PainChek® more in-depth, were measures testing for reliability. The following statistical analyses for reliability were studied:

Interrater reliability (interrater agreement) is a key measure when two tools are tested against each other. Cohen's kappa (Cohen, 1960) statistic is used to measure this type of reliability, which in this study measures the agreement of presence and severity of pain between the two tools. This was assessed overall (pain or no pain) as well as sub-categorised to interrater agreement for no pain, mild pain, moderate pain and severe pain (see table 3.2).

Table 3.2. Strength of interrater reliability as outlined by Cohen (1960).

Strength of agreement	Cohen's kappa (κ) value
No agreement	0
None to slight agreement	.01 to .2
Fair agreement	.21 to .4
Moderate agreement	.41 to .6
Substantial agreement	.61 to .8
Almost perfect agreement	.81 to 1

Intraclass correlation coefficient (ICC) measures the reliability of ratings. The ICC ranges from 0 to 1, where a value closer to 1 indicates a higher similarity between values from the ratings of the same group (see Table 3.3).

Table 3.3. ICC measures for reliability as outlined by (Koo & Li, 2016)

Strength of ICC	ICC value
Poor	Less than .5
Moderate	.5 to .74
Good	.75 to .9
Excellent	Greater than .9

Internal consistency between APS and PainChek® was measured using Cronbach's Alpha. This measure examined whether the two tools were measuring the same constructs. In this study, Cronbach's alpha was used to compare overall scores between the two tools as well as rest and post-movement scores. Bland & Altman (1997) suggest guidelines for Cronbach's Alpha when measuring internal consistency between two research tools, where alpha values of 0.7 to 0.8 are regarded as satisfactory for research tools, and a minimum score is 0.9 is desirable for clinical applications.

The above analytic strategy is in line with previous validation and psychometric evaluation studies for observational pain assessment tools (Cervo et al., 2009; Keela Herr et al., 2019). Specifically, the analytic strategy closely follows and partially replicates the protocol by Atee, Hoti, & Hughes (2018) in a UK care home setting. The measures will collectively indicate the validity and reliability of psychometric properties of the PainChek® when tested against the Abbey Pain Scale.

3.5 Exploring the Atypical Expression of Pain Behaviour in People with Severe Dementia: Case Studies

During the 5-month observational period, the researcher because familiar with painful and pain-free behaviours of residents. The decision to include an additional case study became clear during the 16-week data collection period for the quantitative study. The researcher started to notice behaviour from participants which was not typically reported in the literature. The atypical behaviour was investigated and monitored closely, and it was decided to report the findings of particular participants as case studies, to demonstrate the wide range of perception and experience in pain in people with advanced dementia and therefore provide more depth to this study.

3.5.1 Overview

Three participants out of the cohort of twenty-two demonstrated atypical pain behaviour compared to that reported in the literature. The literature suggests that the main indicators which need to be considered in people with moderate to advanced stages of dementia should not solely focus on verbal expression and pain noises, but instead evaluate all aspects of pain behaviour including sensory, behavioural, emotional and cognitive components (Snow et al., 2004). Guidelines by Hadjistavropoulos, Fitzgerald, & Marchildon (2010) further recommend the continuous use of ongoing and regular evidence-based observational pain assessments for people with dementia. Standardised tools such as the Abbey Pain Scale (developed by Abbey et al., 2004), the Pain Assessment in Advanced Dementia Scale (PAINAD) (developed by Warden, Hurley, & Volicer, 2003), the DOLOPLUS-2 (Chen et al., 2010) or other validated observational pain assessment tools were suggested in the guidelines by Hadjistavropolous et al. (2010).

While the six domains outlined by the AGS are key and provide a good guideline to identifying pain through observation, it is very important to acknowledge that not all

individuals will display their pain behaviour in the same manner. Some of the reported atypical pain behaviours displayed by individuals with moderate-to-severe dementia include aggression, agitation, wandering and calling out (Malotte & McPherson, 2016). Despite literature suggesting that these behaviours are atypical, many observational pain assessment tools account for them, which in turn enhances a more holistic pain assessment approach. However, regardless of the acknowledgement and accommodation for some atypical behaviours presented by people with moderate-to-severe dementia, some individuals will display painful behaviour which is not always accounted for and could be misinterpreted.

The relationship between pain and behaviour (typical or atypical) presented by individuals living with dementia may not always be straightforward to assess, which can create limitations with observational pain assessment tools. In particular, the limitations associated with observational pain assessment tools are linked with factors such as lack of user friendliness where intensive observation is required prior to assessment, non-specificity for pain or failure to detect pain in some individuals due to individual differences and variability in pain expressions (Peisah et al., 2014).

For the reasons outlined above, it is important to look at specific individuals living with dementia more closely and investigate atypical painful behaviour expressed by them. Doing so allows a better understanding of how pain is presented and expressed by individuals living with dementia who demonstrate behaviour which, as outlined by Peisah et al. (2014), varies due to individual differences.

3.5.1.1 Limitations of case studies

Case studies can lack rigour and objectivity in comparison to other research methods (Rowley, 2002), as the author of the case study selects the case studies and can conciously or unconciously present them in a biased way. For example, the author of case studies can consciously or unconsciously forget to report specific elements of individual cases, such as additional comorbidities or dementia behaviours, which may

affect the overall outcome and implementation of findings. Currently, there is no systematic way or a model which can be applied to case studies to ensure objective and rigorous reporting. As it is with the majority of case studies, this case study also does not claim that it can be generalised to the rest of the dementia population. There is no way of knowing to what extent the findings presented in the case study chapter (Chapter 7) are similar or different from other cases of pain presentations in other care homes. There is no way to establish the probability that the case studies presented in this PhD thesis are representative of a larger cohort, and therefore the case study findings might be of little value.

Furthermore, researcher expertise, perception, knowledge and intuition is a crucial part of a case study approach. The researcher chose to focus on questions and issues which seem the most important to answer at the time, therefore making the approach subjective. Additionally, the decision of how the case study stories are presented, which information to include or exclude and how the information is constructed or portrayed is also largely subjective.

Nevertheless, it is important to further investigate case studies such as the ones presented in Chapter 7, especially when one of the overarching aims of this PhD project was to reduce pain presence and severity in people with dementia through the use of a valid and reliable semi-automated pain assessment tool. Those individuals with dementia who do not portray typical painful behaviours should have their pain treated and managed equally to those who portray typical behaviour. To enable such equality in assessing, treating and managing pain in all individuals with dementia, case studies can offer an important insight which can help further develop already existing assessment tools to accommodate for atypical pain behaviours.

3.5.1.2 Strengths of case studies

Despite the limitations outlined above, case studies can also add a unique perspective to research. For example, Eisenhardt (1989) states that case studies are particularly useful to either explore new research areas which have an inadequate theory or for incremental theory building for scientific research. While pain assessment in people

with moderate-to-severe dementia is not a new phenomenon or theory, correct assessment, treatment and management is still largely problematic in terms of pain being under-recognised, under-detected and under-treated (Reynolds, Hanson, DeVellis, Henderson, & Steinhauser, 2008), and therefore case studies such as the ones in Chapter 7 can help highlight the current problems, and offer some solutions.

The research strategy behind case studies are focused on providing answers to “How?” and “Why?” rather than “Who?”, “What?”, “Where?”, “How many?” or “How much?” which are questions more appropriate to be answered by surveys or other experimental methods (Rowley, 2002). In addition to the main focus of case studies being on addressing the question of “why” and “how”, Anderson & Arsenault (1998) see case studies as a method to allow researchers to investigate the difference between the perceived reality, what was planned and what actually occurred. In this case, further exploring the mechanisms or the causes of suboptimal pain assessment, treatment and management in people with dementia may contribute towards addressing and resolving this issue. Therefore, case studies act as an aid to explore the unexpected and the atypical.

The quantitative study (see Chapter 6), focused on providing an answer to whether a newly developed semi-automated pain assessment tool demonstrates good psychometric properties when compared to another observational pain tool. The case study acts as a follow up of this validation study, and focuses on answering the “why” behind atypical pain behaviours observed during data collection, and “how” assessment of those atypical behaviours could be improved or acknowledged better in a typical clinical care routine. This is supported by Noor (2008) who states that case studies as a research methodology are particularly of importance when a specific problem or situation needs to be understood in greater depth.

3.5.2 Aims and objectives

The aim of the case studies is to highlight why investigating individual differences in people living with dementia is important, the need to consider those who do not fit in with the norm and the impact of this on recognition, assessment, treatment and management of pain.

The objectives were:

a) To explore individual differences within people living with dementia and their atypical painful behaviour
b) To offer possible solutions to enhance more accurate pain assessment in individuals presenting atypical pain behaviours

3.6 Summary

This chapter outlined how each element of this PhD thesis was investigated within the four studies. The risk of bias assessment and quality assessment procedures were outlined for the systematic review. The approach undertaken for interview collection and transcript analysis, including the investigation of knowledge of dementia was provided for the qualitative study. The appropriateness of the use of MMSE, the Abbey Pain Scale and the PainChek® were outlined, and the inclusion of cas4e studies was discussed. In addition, this chapter provided a robust explanation and an outline of the methodology undertaken for each of the four studies conducted as part of this PhD thesis. Strengths and limitations as well as appropriateness of the use of each instrument, tool, scale or survey were justified, and an outline of aims and objectives for each element of this thesis was provided. Lastly, a detailed breakdown of statistical and qualitative analysis for each study was provided.

4 Chapter Four - Systematic Review

The Literature Review (Chapter 2) has previously identified some strengths and limitations with currently available observational pain assessment tools. It is important essential to understand what these limitations are in more detail, before further validation PainChek® in the UK, to ensure that the researcher has a thorough knowledge and understanding of both the strengths and the limitations of existing pain tools. This will be an essential learning process, which will result in the ability to not only validate the tool further, but to also critically evaluate and compare it against the accuracy, validity and reliability of already existing tools.

4.1 Introduction

The prevalence of pain increases in adults aged 65 and over, due to chronic pain conditions which are predominantly, but not exclusively, related to the musculoskeletal system, such as arthritis or osteoporosis (International Osteoporosis Foundation, 2017). It is estimated that 60-80% of people with dementia experience regular pain (Corbett et al., 2012, Achterberg et al., 2013), where approximately 70% the pain is nociceptive pain and 25% is a combination of nociceptive and neuropathic pain (van Kooten et al., 2017). One of the common misconceptions about people living with dementia is that individuals do not experience or perceive pain, or that they have a reduced experience of pain in comparison with people who do not have cognitive impairments (Herr, 2010); it is therefore important that pain in people living with dementia is accurately recognised and managed (Bjoro & Herr, 2008).

Advanced stages of dementia are often characterised by aphasia, the progressive loss of language fluency, incorrect pronunciation and use of words and decreased comprehension (National Health Service (NHS), 2017). Self-report subjective measures are no longer considered as reliable for individuals with advanced dementia who are unable to communicate; observational pain assessment tools have been

developed to address the need to correctly assess the presence and severity of pain (Ngu et al., 2015). Currently, there are approximately 18-20 observational pain assessment tools suitable for the assessment of pain in people with dementia across clinical and non-clinical settings (Hadjistavropoulos et al., 2014). The National Institute for Health and Care Excellence (NICE) guidelines encourage health professionals to consider using structured observational pain assessment tool alongside self-reported pain where appropriate, and repeat pain assessment after any pain management intervention or when individuals seem to express behaviour which might be indicative of pain (NICE, 2018). However, while guidelines regarding pain recognition and assessment are provided, there are no general guidelines or recommendation regarding which single observational pain assessment tool should be used universally.

Pain which is not recognised, managed and treated in people living with dementia, is not only a breach of human rights, but can also significantly increase memory decline and progress of the condition (Whitlock et al., 2017). Research by Maxwell et al. (2008) demonstrated that up to 25% of individuals over 65 years of age who experience daily chronic pain and are living in long-term care homes do not receive pain treatment in the form of analgesics. Similar findings have also been reported by Nygaard & Jarland (2005), who found that only 12% of people with dementia were given analgesics and were less likely to receive pain medication compared to individuals without a diagnosis of dementia.

Contrarily, Haasum, Fastbom, Fratiglioni, Kåreholt, & Johnell (2011) challenged the findings by Maxwell et al. (2008) and Nygaard & Jarland (2005), and found that people living with dementia were twice more likely to receive an analgesic compared to people without dementia, despite reporting pain less frequently than people without dementia, and despite the similar prevalence of pain diagnoses in both groups. This has some psychological and clinical consequences and implications. Firstly, majority of the literature seems to indicate that pain is indeed under-treated and poorly managed in people living with dementia, however contradictory reports, such as those from Haasum et al. (2011) might reflect the recently increased awareness of pain treatment and management in individuals with dementia.

The accuracy of an observational pain assessment can be enhanced with an assessor

who is familiar with the pain-free behaviour of the person living with dementia, in order to recognise and interpret the change in such behaviour, and correctly measure presence and intensity of pain (Husebo & Corbett, 2014). Unfortunately, despite a wide range of observational pain assessment tools available, research consistently demonstrates misinterpretation, under-detection and mistreatment of pain in people with dementia (Seitz et al., 2014).

In addition, Zwakhalen et al. (2006) conducted a narrative systematic review which investigated the validity and reliability of observational pain assessment tools for dementia. The findings have shown that many observational pain assessment tools were under-developed and only demonstrated moderate psychometric properties. To the researcher's knowledge, a further systematic review to investigate the progress made since 2006 has not been reported. Hence, one of the rationales for this systematic review is to update the outdated knowledge regarding validity and reliability of observational pain assessment tools which have been developed and validated from 2007 onwards.

Guidelines from the American Geriatrics Society (AGS Panel, 2002) recommend the use of the following six pain domains for an accurate and reliable pain assessment; (1) facial expression, (2) verbalisation/vocalisation, (3) body movement, (4) changes in interpersonal interactions, (5) changes in activity patterns/routines and (6) mental status changes. Since dementia has become a public health priority (World Health Organisation and Alzheimer's Disease International, 2012), research has focused on understanding expressions and behaviours which are indicative of pain in advanced dementia, and decision making related to pain assessment, management and treatment. Based on the literature outlined above, a systematic review was undertaken to address the following question: To what extent are observational pain assessment tools valid and reliable for people with moderate to advanced dementia?

Therefore, the aim of the systematic review was to examine the psychometric properties of observational pain assessment tools, and where available, the influence of the obtained score on the treatment management of pain.

The objectives were:

a) To systematically search appropriate databases to gather articles relating to pain assessment in people living with dementia
b) To evaluate the overall psychometric properties of available observational pain assessment tools, in terms of concurrent validity, interrater agreement, intraclass reliability and internal consistency.
c) To discuss papers which indicate a positive health outcome of observational pain assessment tools in relation to positive health outcomes and cognitive decline, where available.

4.2 Method

The original systematic review was conducted in July 2017, which yielded 12 articles. The systematic was updated on 24th September 2019 at 8:50 am, which yielded additional 6 studies. The sub-sections below reflect the most up-to-date systematic review from September 2019.

Participants, interventions, comparisons and outcomes (PICO) were addressed during the initial stages of this systematic review (see Table 4.1).

Table 4.1. Questions designed in reference to PICO

Type	Description
Participants	Articles must only include participants who are over 65 years of age and must be diagnosed with dementia or have a moderate to severe cognitive impairment.
Interventions	Articles must include observational pain assessment tools designed for either people living with dementia or individuals with

	moderate to severe cognitive impairments who are not able to communicate.
Comparisons	Articles must provide comparisons between tools (e.g. if the aim of the article is to validate a newly developed observational pain assessment tool, comparison between the new tool and the already existing tool must be present). Comparisons in quality of life and health outcomes between pre-intervention and post-intervention were made where possible.
Outcomes	Outcomes included the psychometric properties of observational pain assessment tools (including the level of agreement, inter-rater scores, direct comparisons and any other correlational data). Furthermore, the researchers also investigated positive health outcomes (such as reduction in falls, increased mobility) and quality of life post-intervention.

4.2.1 Inclusion and exclusion criteria

The inclusion and exclusion criteria were developed based on the aims and objectives of this chapter and this thesis. The main aim was to examine the psychometric properties of observational pain assessment tools, and where possible, examine the influence of the obtained score from the observational pain assessment tool on the treatment and management of pain. To do so, some of the criteria focused on the diagnosis of dementia in participants and inclusion of non-invasive pain assessment tool (see Table 4.2).

Table 4.2. Study inclusion and exclusion criteria

Category	Criteria description
Article	Must be peer-reviewed academic journal articles.
Study	Primary quantitative studies, which describe an observational pain assessment tool (qualitative studies, summaries, reviews and other non-primary research studies were excluded).

Participants	Studies must include participants aged 65 years or older, with a diagnosis of dementia (e.g. Alzheimer's Disease).
Instrument	Pain assessment tool must be non-invasive (i.e. observational) and must be designed specifically for dementia or for people with cognitive impairments (e.g. lack of communication skills).
Exclusion criteria	Secondary research studies (e.g. reviews and overviews), case studies, books, conference abstracts.

Common reasons for exclusion of studies included non-peer reviewed publications, full text unavailable, studies which were not written in English language or were published outside the inclusion dates of publication.

4.2.2 Search strategy and databases

Two researchers reviewed relevant studies based on an extensive search strategy, which included searching several online databases. The databases were searched through University of Derby Library Plus database, which subscribes to 231 indexes and databases, including PsycINFO, Medline, Access Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL Plus), PsycARTICLES, Science Direct, Web of Science and others. University of Derby Library Plus accumulates any articles which match with the search criteria and lists all articles within one search engine.

The searches conducted in July 2017 and September 2019 were restricted to full-text articles published between January 2007 and September 2019. Keywords included MESH terms and phrases synonymous with "pain", "dementia", "assessment", "recognition" and "instrument". The searched terms included a combination of; pain, measure*, elder*, pain measure*, cogniti* impair*,dementia, Alzheimer*,pain assess* tool, pain recogni*, alzheim*, instrument, non verbal pain tool.

All articles were assessed and only articles which were written in English language and peer-reviewed were included. These articles were then collated between two researchers who independently conducted second screening of selected articles, using title and abstracts. Additional studies were identified by searching reference lists of academic journal articles which were identified in the second screening phase. Both researchers have then accepted or rejected articles based on the previously outlined inclusion and exclusion criteria.

The following two Boolean searches were used in University of Derby Library Plus database. The words and phrases were applied to titles only:

1. TITLE: (pain measure* elder*) OR TITLE: (pain measure* cogniti* impair*) OR TITLE: (pain measure* dementia) OR TITLE: (pain measure* alzheimer*)

2. TITLE: (pain assess* tool dementia) OR TITLE: (pain recogni* alzheim* instrument) OR TITLE: (non verbal pain tool)

4.2.3 Screening

The systematic review consisted of two screening phases, both of which were independently completed by two researchers. The first screening phase included screening titles only for relevance. If titles were clearly not relevant, i.e. it was clear from the title that the target participant cohort were not people with dementia, then the article was excluded. If, based on the title of the article, it was not clear whether the article met the inclusion and exclusion criteria, it would proceed to screening 2 stage where the abstract was also assessed.

The second stage was also completed independently by two researchers. The articles needed to meet all exclusion criteria. Once the screening process was completed individually, the two researchers had discussed the inclusion and exclusion of all articles. There was no disagreement between the two researchers. The included articles were then assessed for quality and bias.

The original systematic review search, conducted in July 2017, generated 198 articles, with additional 37 articles identified by hand searching the reference lists. The updated systematic review search, from September 2019, identified further 56 articles and 1 additional article through hand searching references, totalling 254 records identified through database searching and 38 additional records identified through hand searching reference lists. Duplicates were removed and subsequently, two authors conducted a two-step inclusion/exclusion process; step one consisted of screening titles and abstracts of articles, step two consisted of screening full-text articles. All articles were screened based on agreed inclusion and exclusion criteria. After completing both screenings, 17 articles were included in this systematic review (see figure 4.1).

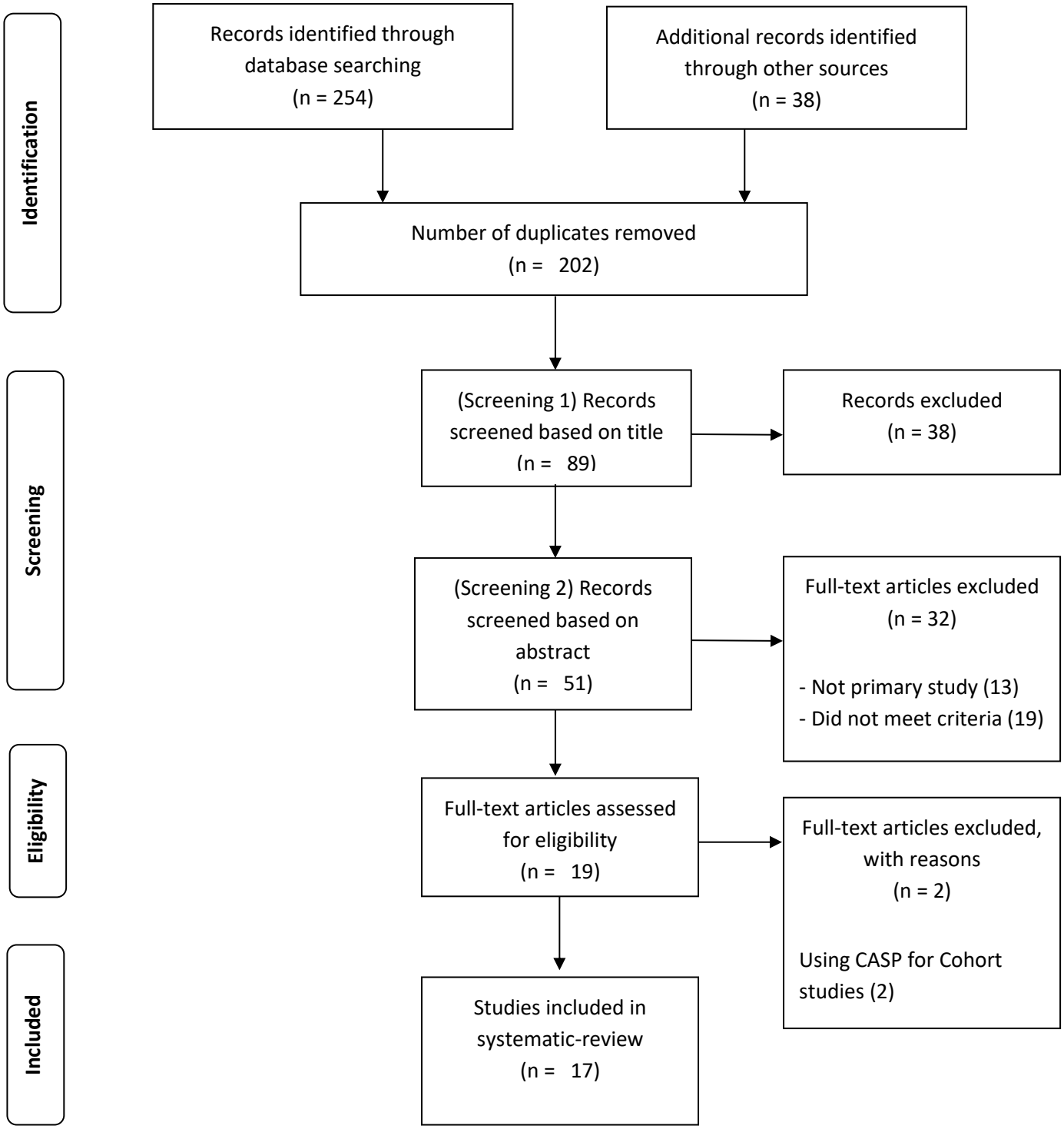

Figure 4.1. PRISMA Flow diagram (Moher, Liberati, Tetzlaff, & Altman, 2009) of included and excluded articles with reasons

4.2.4 Quality assessment

Research suggests that the quality of health research reports is poor and that reporting guidelines should not only be endorsed, but also implemented to enhance the transparency and clarity of key findings (Turner, Shamseer, Altman, Schulz, & Moher, 2012). Hence, two checklists were implemented to assess the quality of included articles. These were the Template for Intervention Description and Replication (TIDieR) and the Critical Appraisal Skills Programme (CASP, 2017). The TIDieR checklist is a 12-item checklist (see table 4.3) which was developed by a panel of international team of experts, with the aim to promote more accurate description and evaluation of trial intervention studies (Hoffmann et al., 2014).

While the emphasis of the TIDieR is on interventions in randomised clinical trials (RCTs), the items are designed to apply across all evaluative study designs (Hoffmann et al., 2014). The TIDieR checklist has been useful in providing a structure to help identify the aspects of the observational pain assessment tools which were either clearly reported, were unclear or missing altogether. The 12 items were examined for each included article by two researchers independently. The two researchers then compared results from the TIDieR checklist and discussed any disagreements (for completed TIDieR checklist see table 4.4).

Table 4.3. The 12 items used in the TIDieR checklist, taken from (Hoffmann et al., 2014).

TIDieR item	Brief description.
Brief name	Name or phrase describing the intervention.
Why	Rationale, theory, or goal of elements essential to intervention.
What (materials)	Physical or informational materials used, and where they can be accessed.

What (procedure)	Procedures, activities, and/or processes used in the intervention, including any enabling or support activities.
Who provided	Background, expertise of the provider, and training given.
How	Modes of delivery, delivered to group or individual.
Where	Type of location.
When and How much	Number of times, number of sessions, intensity and over what time period delivered.
Tailoring	What, why, when, and how of planned personalisation or adaptation.
Modification	What, why, when and how of intervention modification during study.
How well (planned)	If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity.
How well (actual)	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

The quality of the included studies was assessed using CASP, which is a 12-item tool designed to help researchers critically appraise articles. If the first two questions, which focus on critically assessing whether the studies addressed a clearly focused issue and use an appropriate recruitment strategy, are answered as either “no” or “can’t tell”, the checklist encourages the assessor to consider whether the evaluation is worth continuing. If the assessor deems the article as not worthy of further evaluation, the article may be removed from the overall systematic review due to poor

quality. To reduce bias, two researchers completed CASP checklist for each included study independently and then discussed the result. Subsequently two studies were excluded:

1. a study by Fuchs-Lacelle & Hadjistavropoulos (2004), where caregivers participating in the study were asked to report pain from memory, which acted as a baseline for development of PACSLAC. No participants with dementia were included in this study.

2. a study which focused on views and perceptions of paramedic students for two pain assessment tools rather than psychometric properties or effectiveness of observational pain assessment tools in general (Lucas et al., 2016).

Table 4.4. TIDieR framework for all studies included in this systematic review, sorted by total number of items marked as "yes".

Study	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12
Atee et al. (2017)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	yes
Hoti et al. (2018)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	yes
Cervo et al. (2007)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	yes
Monacelli et al. (2013)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	yes
Horgas et al. (2007)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	yes
Jordan et al. (2011)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	yes
Husebo et al. (2007)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	yes	yes	yes
Pautex et al. (2007)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	yes	yes	yes
Rat et al. (2011)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	yes	yes	yes
Atee et al (2018)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	n/a	yes	yes

Monacelli et al. (2016)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	n/a	yes	yes
Mahoney et al. (2008)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	n/a	yes	yes
Cervo et al. (2009)	yes	yes	unclear	yes	yes	unclear	yes	yes	n/a	n/a	yes	yes
Pickering et al. (2010)	yes	yes	yes	yes	yes	yes	yes	unclear	n/a	n/a	yes	yes
Lints-Martindale et al. (2012)	yes	yes	yes	yes	unclear	yes	yes	yes	n/a	n/a	yes	yes
Likar et al (2015)	yes	yes	yes	unclear	yes	unclear	yes	yes	n/a	n/a	yes	yes
Cervo et al. (2012)	yes	yes	yes	yes	yes	yes	yes	yes	n/a	n/a	yes	unclear

Notes: yes – clear description of item; no – minimal or no description of item; unclear - unclear description of item; n/a – the design of the study voided the relevance of this item

Item 1: Brief name (Provide the name or a phrase that describes the intervention)
Item 2: Why (Describe any rationale, theory, or goal of the elements essential to the intervention)
Item 3: What (Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed).
Item 4: What (Procedures: Describe all procedures, activities, and processes used, including any enabling or support activities).
Item 5: Who provided (For each category of intervention provider, describe their expertise, background and any specific training given).
Item 6: How (Describe the modes of delivery) of the intervention and whether it was provided individually or in a group).
Item 7: Where (Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or features).
Item 8: When and how much (Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose).

Item 9: Tailoring (If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how).
Item 10: Modifications (If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)).
Item 11: How Well (Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them).
Item 12: How well - Actual: If intervention adherence or fidelity was assessed, describe the extent to which it was delivered as planned).

4.2.5 Bias screening

Once the quality assessment for each included study was completed, two researchers independently investigated each article for the following five biases: performance bias, detection bias, attrition bias, reporting bias and selection bias (see table 4.5 for an outline and description of each bias).

Table 4.5. Description of each bias assessed in this systematic review

Type of bias	Example	Brief description
Selection bias	Random sequence generation and allocation concealment	Could the reporting have been impacted by participants or practitioners knowing which was the experiment and control groups.
Performance bias	Blinding of participants and personnel	Were those scoring the outcomes (either participant or practitioner) aware of the groups?
Detection bias	Blinding of outcome assessment	Do the authors reasonably explain how they managed drop out data in the study
Attrition bias	Addressing incomplete outcome data	Was there evidence that the authors omitted measures or data to present more favourable results?
Reporting bias	Selective reporting	Could the authors be revealing or suppressing information selectively?

Risk of bias assessment is important when reviewing individual articles in a systematic review, as it establishes the transparency of results and findings. Cochran Collaboration warns against using a scoring system in the risk of bias assessment scales; therefore the two assessors used a simple judgement to indicate whether each bias was present, and if so whether it was low, high or unclear (see table 4.6).

Table 4.6. Independently co-reviewed bias risk assessment for all studies included in Systematic review

	Atee et al. (2017)	Likar et al. (2015)	Hoti et al. (2018)	Cervo et al. (2007)	Monacelli et al. (2016)	Monacelli et al. (2013)	Mahoney et al. (2008)	Lints-Martindale et al.	Horgas et al. (2007)	Husebo et al. (2007)	Cervo et al. (2009)	Pautex et al. (2007)	Pickering et al. (2010)	Cervo et al. (2012)	Jordan et al. (2012)	Rat et al. (2011)
Selection bias	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Performance bias	L	U	L	L	U	L	L	L	L	L	L	L	L	U	L	L
Detection bias	L	U	L	L	U	L	L	L	L	L	L	L	L	U	U	L
Attrition bias	L	U	L	L	U	U	L	L	U	U	L	U	L	L	L	L
Reporting bias	U	L	U	L	L	L	L	U	L	L	L	L	L	L	L	L

Key: L = low risk of bias, H = high risk, U = unclear risk

4.2.6 Data extraction

Relevant information, including validity, reliability and demographic information were extracted into an Excel spreadsheet from each study. The content of articles was extracted using a data-extraction table, which was developed, piloted and discussed with another researcher. Two researchers then independently extracted each article and discussed any sections of articles which were not clearly stated or explained. There was no disagreement between the two researchers regarding included articles.

The extracted validity and reliability measures focused on extracting values used to report psychometric properties of instruments, including concurrent validity (Pearson's and Spearman's correlation coefficients), interrater agreement (Cohen's Kappa) and internal consistency (Cronbach's Alpha).

The demographic information included extracting data about participants; sample size, mean age with standard deviation, percentage of participants which had a diagnosis of dementia, mean score and standard deviation of MMSE (if reported), country where the study was conducted, the setting and the observational pain assessment tool(s) used. The studies, which did not report psychometric properties, were included in a narrative review, but excluded from the meta-analysis which focused on validity and reliability measures.

4.2.7 Analytic strategy

Several methods and measures were examined to analyse the results from the meta-analysis. A meta-analysis is a quantitative and formal type of study design used to systematically analyse previous research to make conclusions about a particular field or body of research (Haidich, 2010). In this case, investigation of the publication bias was included from Meta-Essentials 1.5 (Van Rheem, Suurmond, & Hak, 2015) in terms

of examining a funnel plot and applying the trim-and-fill method where appropriate and exploring the heterogeneity and homogeneity of meta-analysis results.

A funnel plot is a form of a scatter plot, which estimates the treatment effect from individual studies against standard error (SE), where asymmetry in the funnel plot may represent a potential publication bias (Mavridis & Salanti, 2014b). However, Mavridis & Salanti (2014b) also state that an asymmetrical funnel plot could also have other explanations, such as heterogeneity, chance or selective outcome reporting. Additionally, while a meta-analysis can help examine presence and sources of heterogeneity which can lead to better treatment and prevention strategies, if heterogeneity is present it should be interpreted with caution (Greenland, 1987).

To symmetrise the results in the funnel plot, a trim-and-fill method was used. The trim-and-fill method identifies publication bias and adjusts the results by either excluding (trimming) small studies or replicating (filling) them, with the aim to create a more symmetrical funnel plot (Mavridis & Salanti, 2014a). However, in a similar way to the funnel plot, the trim-and-fill method makes a strong assumption that asymmetry is caused by publication bias, rather than heterogenic results in a meta-analysis, and therefore

The data were entered into Meta-Essentials Excel Spreadsheet developed at Erasmus Research Institute of Management (Van Rheem et al., 2015), using spreadsheet 5 Meta-Essentials Correlational data version 1.5.

4.3 Results

The 17 studies included in the review provided a total sample size of N = 2007, of which 64.12% were female. The mean age was 83.51 years across all studies (Table 4.7). This male to female ratio is anticipated for this population and in line with the average higher life expectancy for females (Office for National Statistics, 2016). The analysis of the articles included in this review identified that 83.51% had a formal

diagnosis of dementia. Eleven studies collected Mini-Mental State Examination (Folstein et al., 1975a) scores to assess the severity of impairment in participants. The mean Mini-Mental State Examination (MMSE) scores across these studies were 12.3, indicating moderate cognitive impairment. The MMSE mean for a single study ranged from 4.3 (Lints-Martindale, Hadjistavropoulos, Lix, & Thorpe, 2012) to 18 (Pautex, Herrmann, Michon, Giannakopoulos, & Gold, 2007).

Table 4.7. Descriptive information about included studies

Article	Sample size	% female	Mean age (SD)	% w/ dementia	Country	Mean MMSE score	Setting	Pain Instrument
Atee et al. (2017)	37	58.8%	85.5 (6.3)	100.0%	Australia	-	Aged care facility	ePAT
Likar et al. (2015)	127	69.0%	81.8 (6.9)	100.0%	Germany	19.8	Geriatric department and department of psychiatry and psychotherapy	Doloshort
Atee et al (2018)	10	50.0%	74.4 (5.9)	100.0%	Australia	-	Aged care facility	ePAT
Hoti et al. (2018)	37	58.8%	85.5 (6.3)	100.0%	Australia	-	Aged care facility	ePAT
Monacelli et al. (2016)	96	55.0%	81.0 (NR)	100.0%	Italy	20.1	University hospitals	Algoplus®
(Lints-Martindale et al., 2012)	124	88.0%	83.9 (7.6)	100.0%	-	5.4	Long-term care facility	CNPI, PACSLAC, PADE, PAINAD, NOPPAIN
(Horgas et al., 2007)	40	77.5%	83.0 (NR)	50.0%	USA	17.0	Community, Assisted living, nursing home	NOPPAIN

(Monacelli et al., 2013)	23	78.3%	88.1 (2.4)	100.0%	Italy	10.3	Nursing home	Doloplus-2
(Husebo et al., 2007)	26	88.5%	87.0 (6.1)	100.0%	Norway	4.3	Nursing home	MOBID
(Cervo et al., 2009)	145	50.3%	84.3 (NR)	100.0%	USA	7.8	Veterans Home, Residential home	CPAT
(Pautex et al., 2007)	180	173.9%	82.0 (NR)	73.0%	Switzerland	18.0	Hospital	Doloplus-2
(Pickering et al., 2010)	90	66.7%	84.0 (7.8)	100.0%	UK	12.0	Nursing home, Long-term care setting, acute care	Doloplus®
(Mahoney & Peters, 2008)	112	77.7%	85.4 (7.9)	100.0%	Australia	-	Nursing home	Mahoney Pain Scale
(Cervo et al., 2012)	215	47.9%	84.9 (7.2)	100.0%	USA	8.4	Nursing and rehabilitation centre, veterans home and residence home	CPAT
(Jordan et al., 2011)	90	72.0%	82.0 (8.14)	100.0%	UK	-	Nursing home	PAINAD
(Cervo et al., 2007)	182	52.0%	81.0 (NR)	100.0%	USA	-	Skilled nursing facility, veterans home	CPAT
(Rat et al., 2011)	349	61.0%	81.6 (8.0)	32.0%	France	<15	Emergency departments, non-geriatric and geriatric acute settings, rehab units and long-term care facilities	Algoplus®

Note: NR = not reported

4.3.1 Meta-analysis

Concurrent validity, in terms of Pearson's or Spearman's correlation coefficients, were reported by 12 out of the 17 studies which met inclusion criteria for this systematic review. Reliability measures of psychometric properties in terms of Cronbach's alpha (Bland & Altman, 1997) were only reported by 8 studies, and Cohen's kappa measures (Cohen, 1960) were only reported by 9 studies (see table 4.8). Therefore, only studies, which reported the aforementioned measures, were included in the retrospective meta-analyses. Meta-Essentials version 1.5 (Van Rheem et al., 2015) was used to complete the meta-analysis for this systematic review.

The studies which did not report any of the above values were excluded from the meta-analysis but have still been included in the overall discussion later in this chapter. The excluded studies included:

1. Hoti, Atee, & Hughes (2018) who reported clinometric properties of ePAT, rather than psychometric properties

2. The study by Monacelli et al. (2013) which investigated change in prescription of analgesics after the Doloplus-2 has been adapted in nursing homes

3. Cervo et al. (2012) whose main aim was to implement CPAT as an intervention and investigate changes in number of falls, episodes of distressed behaviours and changes in administered antipsychotic medication

4. A study by Cervo et al. (2007) aimed to develop a pain assessment tool but did not evaluate its psychometric properties

5. A study conducted by Jordan et al. (2011) focused on reducing pain through implementation of PAINAD rather than evaluating psychometric properties.

Table 4.8. Statistical information extracted from included studies

Study (Pain instrument)	Concurrent validity (Pearson's or Spearman's)	Reliability measures (Cronbach's alpha)	Reliability measures (Cohen's Kappa)
Atee et al. (2017) (ePAT)	0.91	0.95	0.86
Atee et al. (2018) (ePAT)	0.92		0.80
Cervo et al. (2009) (CPAT)	0.25	0.77	0.65
Horgas et al. (2007) (NOPPAIN)	0.63	0.95	0.91
Husebo et al. (2007) (MOBID)	0.91	0.90	0.46
Likar et al. (2015) (Doloshort)	0.96		
Lints-Martindale et al. (2012) (CNPI, PACSLAC, PADE, PAINAD, NOPPAIN)	0.73	0.52	0.81
Mahoney et al. (2008) (Mahoney Pain Scale)		0.76	0.87
Monacelli et al. (2016) (Algoplus®)	0.78		
Pautex et al. (2007) (Doloplus-2)	0.46	0.67	0.60

Pickering et al. (2010) (Doloplus®)	0.86
Rat et al. (2011) (Algoplus®)	0.30

Concurrent validity measures how well a new pain assessment tool compares to a well-established pain assessment tool, in terms of the scores given for presence and severity of pain. Low concurrent validity indicates that the new tool is either detecting presence of pain when the well-established tool is not, or that the severity of pain detected by the new tool is different to that detected by the well-established tool (or vice versa). High concurrent validity suggests that the new tool and the already established tool both detect similar levels of presence and severity of pain. For example, from the table above, ePAT (Atee et al., 2018) demonstrated a high concurrent validity score, suggesting that the correlation between ePAT and Abbey pain Scale (the well-established tool) was high in terms of presence and severity of pain detected by both tools, compared to Algoplus® (Rat et al., 2011) which indicated a low concurrent validity.

Cronbach's alpha is a reliability measure which measures internal consistency, or how well a tool measures what it should measure. In this case, the measure was used to gauge whether the new tool and the well-established tool were measuring the same constructs. High Cronbach's alpha suggests that the items included within the pain assessment tools are representative of the pain domain, compared to low Cronbach's alpha which suggests that the items (domains) within the observational pain assessment tools may not be measuring the same construct. For example, the extracted statistical data suggested that both ePAT (Atee et al., 2017) and NOPPAIN (Horgas et al., 2007) included constructs which were highly representative of the behaviour and domain items measured.

The final measure of reliability extracted from the included studies was Cohen's Kappa, which is a measure used to investigate interrater reliability, sometimes referred to as interrater agreement. This measure is used when two pain assessors each rate

one pain assessment per each observation. A low Cohen's Kappa value suggests that the two individual assessors did not agree on presence and severity of pain for the individual observed, whereas a high value suggests otherwise. The higher the Cohen's Kappa score, the stronger the agreement. For example, NOPPAIN (Horgas et al., 2007) had demonstrated a near perfect agreement, compared to MOBID (Husebo et al., 2006) which only demonstrated a moderate agreement of presence and severity of pain between two independent assessors.

Three meta-analyses were conducted. Each investigated a specific aspect of the psychometric properties of observational pain assessment tools, in terms of validity (concurrent validity) and reliability (inter-rater agreement and internal consistency).

4.3.1.1 A meta-analysis of concurrent validity

The first meta-analysis investigated the concurrent validity based on the studies, which met criteria for the systematic review. The statistical meta-analysis suggested heterogeneous correlational data (Q= 381.05, p= <.001, I^2 = 97.11%) indicating that there is a variation and inconsistency between the concurrent validity in the included studies. The overall correlation for combined effect size was 0.76. The calculation of I^2 indicated a high level of variability therefore suggesting a high level of heterogeneity. Additionally, publication bias of the meta-analysis was further investigated by examining a funnel plot (see Figure 4.2).

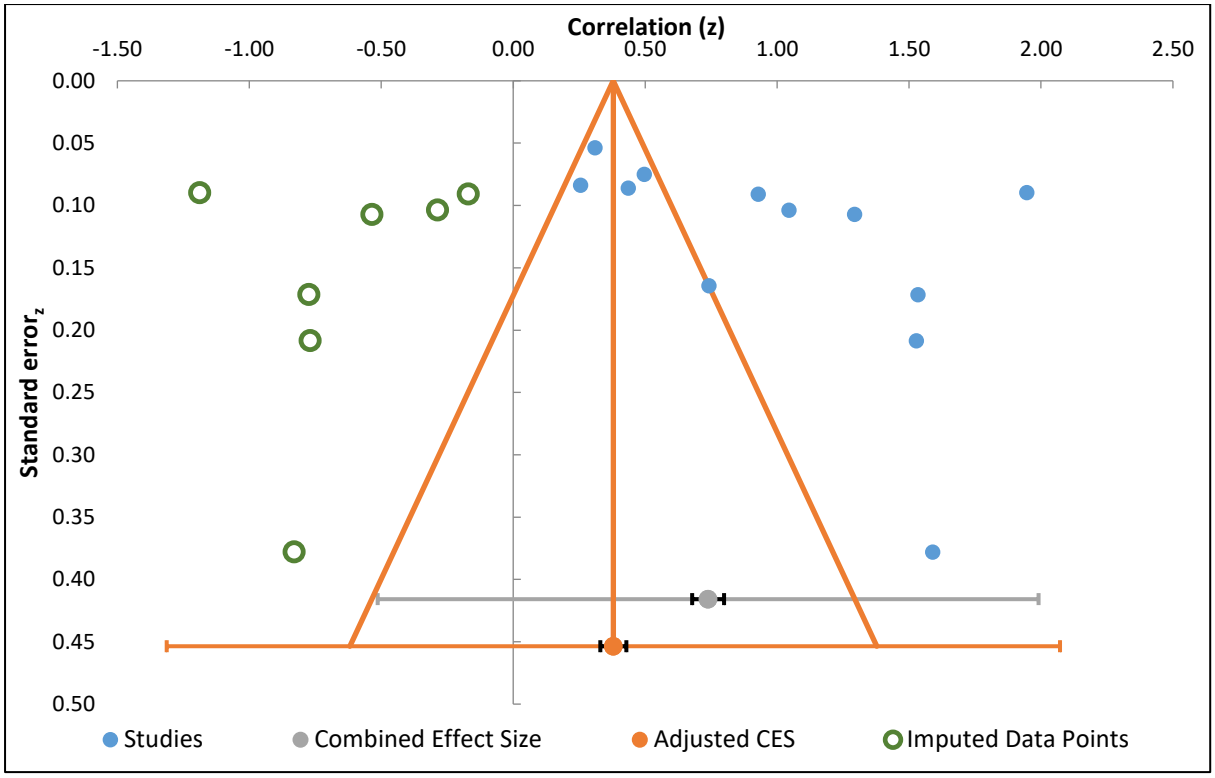

Figure 4.2. Funnel plot for Pearson's and Spearman's correlation coefficients for the studies included in this meta-analysis (with trim & fill function)

In this case, the trim and fill method imputed seven data points to increase symmetry of the funnel plot, which resulted in adjusted meta-analysis results (Q= 1092.5705, p= <.001, I^2 = 98.35%). Thus, the confidence intervals (CI) have decreased from pre-fill and trim method (lower limit CI = 0.68, upper limit CI = 0.80), to post-fill and trim method (lower limit CI = 0.33, upper limit CI = 0.43).

Additionally, a breakdown of the concurrent validity measures was investigated. Validity was measured using the following values; Pearson's correlation coefficients and Spearman's rank correlation coefficients. All correlation coefficients demonstrated a positive correlation, with the strongest positive correlation of .92 and lowest of 0.25, further evidencing the heterogeneity of the results illustrated in the funnel plot above.

4.3.1.2 A meta-analysis of interrater agreement

The second meta-analysis investigated the inter-rater agreement, specifically in terms of reported Cohen's Kappa (Cohen, 1960). Cohen's Kappa for inter-rater agreement is measured on a scale of 0 to 1, where a higher score demonstrates stronger agreement between two raters or two tools.

The statistical meta-analysis, based on 9 studies and 812 subjects, also suggested heterogeneous correlational data (Q= 64.54, p= <.001, I^2 = 87.6%) indicating that there is a high variation and inconsistency for Cohen's kappa scores. The overall correlation for combined effect size was 0.93. In a similar way to the above meta-analysis concurrent validity, the calculation of I^2 also indicated a high level of variability and a high level of heterogeneity, which was confirmed when a funnel plot was investigated (see Figure 4.3).

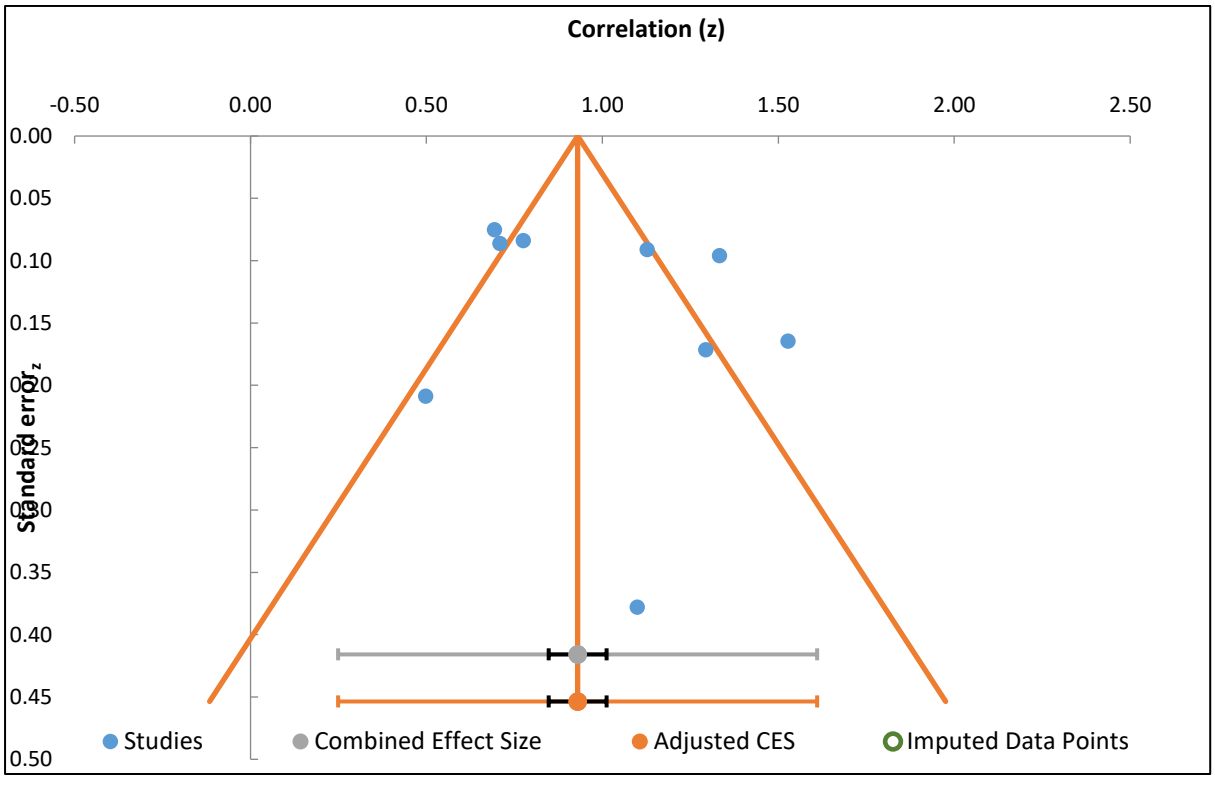

Figure 4.3. Funnel plot for Cohen's Kappa correlation coefficients

Unlike the previous funnel plot, the trim-and-fill method was not applied to this meta-analysis, as although the data were heterogeneous, they were far more symmetrical than the results for concurrent validity. Thus, the 95% CI were 0.85 for the lower limit and 1.01 for the upper limit. Furthermore, a detailed breakdown of the interrater agreement was investigated by looking at Cohen's Kappa (*K*) values. Eight of the included studies included a *K* measure, ranging from 0.46 to 0.91.

4.3.1.3 A meta-analysis of internal consistency

The final meta-analysis investigated Cronbach's alpha (Bland & Altman, 1997), which measures internal consistency. Internal consistency is a correlation coefficient, which measures whether two tools, which use the same or similar scoring system, measure the same construct.

Eight studies with 780 subjects were included in this meta-analysis. Similarly to the previous two meta-analyses, the results for Cronbach's Alpha correlation coefficient also demonstrated heterogeneous results (Q= 70.53, p= <.001, I^2 = 90.07%) which was confirmed with a funnel plot. The overall correlation for combined z score effect size was 1.14, with the lower limit 95% CI of 1.06 and upper limit of 1.23. The trim-and-fill function imputed one study (see figure 4.4), to increase overall symmetry of the inputted results. This decreased the upper and lower limits of CI (1.04; 1.21). Furthermore, the individual α scores were also investigated in this meta-analysis. The lowest reported α was 0.52 compared to the highest score of α= 0.95.

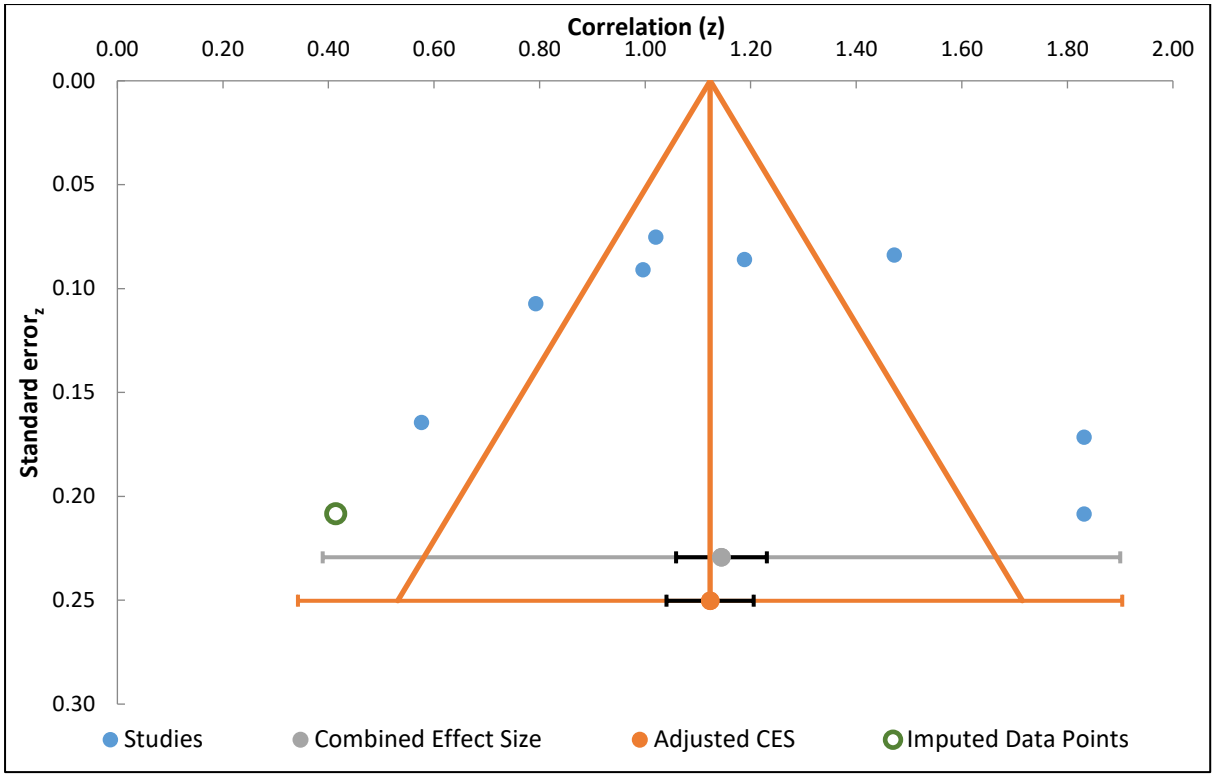

Figure 4.4. Funnel plot for Cronbach's Alpha correlation coefficients (with trim-and-fill function)

4.3.2 Narrative review

The studies which did not report any psychometric properties and were therefore excluded from the meta-analysis, as well as the studies which were included in the meta-analysis, were also reviewed and reported. While the meta-analysis focused on statistical analysis of the included articles, the narrative review focused on the pain domains implemented in each observational pain assessment tool, and if the information from the assessment studies was used to alter pain medication plans. The following questions were answered below:

Which pain domains do the observational pain assessment tools use to obtain accurate presence and severity scores of pain in individuals with dementia or cognitive impairments?

Do observational pain assessment tools result in an accurate treatment of pain (e.g. recognised pain is correctly treated with analgesics or another method of treatment and management of pain)?

Does correctly recognised and treated pain in people with dementia/cognitive impairment result in a positive health outcome?

4.3.2.1 Pain domains

All observational pain assessment tools were compared against the AGS's recommendation of the main six pain domains. Table 4.9 demonstrates the domains which were included by each observational pain assessment tool from the studies included in this systematic review. Only two observational pain assessment tools; Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) and ePAT included all six pain domains recommended by the AGS. Moreover, only three domains; facial expression, body movement and vocalisation/verbalisation, were used by all 11 observational pain assessment tools. Changes in activity patterns was included in 54.5% of the tools, mental status changes by 45.5% and changes in interpersonal interactions only by 36.4% observational pain assessment tools.

It is also important to note that the Mahoney Pain Scale (MPS) also included an additional domain; the physiological changes, which consisted of temperature change, pulse or blood pressure outside normal limits, perspiration and flushing or pallor. This is consistent with the Abbey Pain Scale (Abbey et al., 2004).

Table 4.9. The pain domains included in individual observational pain assessment tools used in the articles included in the present systematic review

	Pain domain					
Name of the observational pain assessment tool	Facial expression	Body movement	Vocalisation	Changes in interpersonal	Changes in activity patterns	Mental status changes
Checklist of Nonverbal Pain Indicators (CNPI) (Feldt, 2000)	Y	Y	Y	N	N	N
Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) (Fuchs-Lacelle & Hadjistavropoulos, 2004)	Y	Y	Y	Y	Y	Y
The Pain Assessment for the Dementing Elderly Scale (PADE) (Villanueva et al., 2003)	Y	Y	Y	N	Y	Y
Pain Assessment in Advanced Dementia (PAINAD) (Lane et al., 2003)	Y	Y	Y	N	N	N
The Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN)	Y	Y	Y	N	N	N

(Snow et al., 2004)						
Doloplus-2 (Lefebvre-Chapiro, 2001)	Y	Y	Y	Y	Y	N
Mobilization-Observation-Behaviour-Intensity Dementia Scale (MOBID) (Husebo et al., 2007)	Y	Y	Y	N	N	N
Certified Nursing Assistant Pain Assessment Tool (CPAT) (Cervo et al., 2007)	Y	Y	Y	N	Y	Y
Mahoney Pain Scale (MPS) (Mahoney & Peters, 2008)	Y	Y	Y	Y	Y	N
Algoplus® (Rat et al., 2011)	Y	Y	Y	N	N	Y
PainChek® (previously known as Electronic Pain Assessment Tool (ePAT) (Atee et al., 2017)	Y	Y	Y	Y	Y	Y

Key: Y – pain domain included in the observational pain assessment tool; N – pain domain not included in the observational pain assessment tool

4.3.2.2 Appropriateness of pain treatment

Another element of pain recognition investigated in the narrative component of this systematic review looked at how the pain scores from the observational pain assessment tool were utilised and whether they contributed to an alteration of medication in terms of pain treatment and management.

Only three studies investigated and reported changes in analgesics prescription and intake in participants with dementia, with pre and post-intervention comparisons. Monacelli, Vasile Nurse, Odetti, & Traverso (2013) reported that prior to introducing Doloplus-2 and at initial assessment, only 30% of individuals living with dementia received analgesics for pain. After implementation and regular use of Doloplus-2, a 1-year follow up demonstrated that the pain symptoms in participants has reduced significantly as a result of regularly assessed pain, which helped assessors treat and manage pain more effectively. Furthermore, the authors have reported a 57% reduction of pain behaviours in participants after 1-year of routine use of the pain Dolplus-2, suggesting that analgesic prescription has been altered based on the scores from the observational pain assessment tool, which in turn resulted in reduction of pain behaviours exhibited by participants.

Another study which utilised scores from an observational pain assessment tool to enhance pain management and treatment was conducted by Jordan, Hughes, Pakresi, Hepburn, & O'Brien (2011). Thirteen participants living with dementia were assessed for presence and intensity of pain using the PAINAD. The baseline scores obtained from the PAINAD were used to develop an intervention, which was a personalised pain management plan for each participant. All participants with the personalised pain management plan had a follow-up PAINAD assessment after one and three months. The follow-up PAINAD scores demonstrated a significant decrease of pain as a result of implementation of the intervention. This was also demonstrated by Rat et al. (2011) who reported lower pain scores and symptoms post-treatment of pain in hospitalised patients with acute pain using Algoplus®.

It was noted that although some studies in this review reported the use of analgesics, the scores from observational pain assessment tools did not affect the dose of analgesics administered to people living dementia. For example, Husebo et al. (2007) included statistics about analgesics and opioids, but the scores from the observational pain assessment tool were not used to adjust the treatment and management plans. In other words, Husebo et al. (2007) reported that 96% of participants were receiving one or more analgesics and 19.2% received an opioid, however this information was only reported as a demographical statistic.

However, it has been recognised that the primary aim of the above studies included in this review was typically to evaluate psychometric properties or to validate an observational pain assessment tool rather than use the scores from the tool to adjust treatment and pain management plan. Nevertheless, this demonstrates that observational pain assessment tools might not always be used to their full potential in research, and the scores collected from the tools might not always be used to design or tailor a pain treatment and management plan for individuals.

4.3.2.3 Positive health outcomes

The definition for positive health outcomes has not been established, and while there are some discussions surrounding the meaning of this term, Locker & Gibson (2006, p. 164) state that “the most common and simplest way in which positive health has been framed is in terms of the absence of negative health states. Most measures of health status assess the presence and by implication the absence of problems in physical and psychological functioning”. In this case, positive health outcomes will refer to aspects of physical and psychological functioning such as improved quality of life, wellbeing, decreased number of falls or other elements. Therefore, from the literature outlined in the Literature Review (Chapter 2), it can be suggested that accurately recognised, assessed, treated and managed pain can often result in positive health outcomes such as increased mobility, quality of life, increased activities of daily living and even happiness. It is therefore of importance to further investigate whether the use of the pain assessment tools included in this systematic review did

report any positive health outcomes as a result of accurately recognised, assessed and treated pain.

Cervo et al. (2012) investigated how the observational pain assessment tool increases the number of positive health outcomes in terms of decrease of falls, episodes of distressed behaviour and rates of antipsychotic medication use. The aim was to determine whether observational pain assessment tools aid effective pain management strategies, and consequently lead to a decrease in falls. The researchers reported 206 falls at baseline, compared to a 114 falls at follow-up, demonstrating a 21.1% decrease of falls over a 3-year period. The administration of antipsychotics was also decreased by 51% (orders for antipsychotics have reduced from 303 to 164 over the three years, and percentage of time spent on antipsychotic reduced from 42.2% to 20.7%). Although distressed behaviour such as verbally aggressive episodes was also decreased over the 3-year period, the number distressed behaviours such as physically aggressive episodes, physically nonaggressive episodes, and verbally nonaggressive episodes have increased significantly.

4.4 Discussion

The aim of this systematic review was to examine the psychometric properties of observational pain assessment tools, and where available, the influence of the obtained score on treatment and management of pain in people with dementia. Eighteen articles were identified through a systematic search of databases and indexes. The search also identified 11 observational pain assessment tools which are currently used worldwide. Before summarising and discussing the implication of the findings, it is important to note that this systematic review only focused on one element of observational pain assessment. Therefore, it must be noted that this is only a small aspect in pain assessment for people with dementia and that the findings need to be interpreted carefully. Pain assessment, especially for people with dementia, is very complex and observational pain assessment tools only form a small part of the full pain treatment and management process. Being able to investigate the psychometric properties of observational pain assessment tools is important, however, there are

other elements such as training, education, workload and paperwork which have not been considered or investigated in this review. The discussion below will only focus on summarising the key findings from the aspect which has been investigated in detail.

The funnel plots across the three validity and reliability measures have shown highly heterogenous results, indicating a possibility of publication bias or highly varying reported statistical values across the studies. Publication bias refers to lack of systematic representation of the studied population (Rothstein et al., 2005). For example, with majority of studies were plotted to the right side of adjusted Combined Effect Size (CES) line for concurrent validity (Figure 4.2), reiterating the asymmetry in the distribution of the effect sizes. The trim-and-fill function has imputed seven data points to the left of the adjusted CES line for the potentially missing studies. However, while the varying validity and reliability results can be seen from the funnel plots, especially for concurrent validity (Figure 4.2), it's also important to note that these results must be interpreted with caution. The distribution of the individual studies is expected to fall within the triangular lines for homogenous meta-analyses.

Some of the heterogeneity, in terms of reported validity and reliability results, found within this meta-analysis could be explained by the settings and populations within which the results and pain assessments were collected. For example, the older population age at different rates and have different genetic backgrounds, medical conditions, level of cognitive impairment or deterioration, therefore making this population highly heterogenous (Kojima, 2015). In addition, the setting across the studies also varied greatly, from nursing homes and aged care facilities to hospitals and emergency hospitals. The combination of the wide variety of population and setting could have impacted the results of the meta-analysis in general. In addition, as previously mentioned, this finding needs to be interpreted carefully. The heterogeneity of the reported psychometrics could potentially be explained by other factors such as inappropriate or sub-optimal use of the observational pain assessment tool due to high workload in care homes and hospitals, rather than lack of validity, reliability and accuracy of the tool investigated.

The I^2, which is a method to quantify heterogeneity, was also investigated. The I^2 is reported as a percentage of total variation across studies which is due to heterogeneity

rather than chance (Neyeloff et al., 2012). All I^2 values above 75% are classed as high (Higgins et al., 2003), which was the case for all three validity and reliability measures in this meta-analysis, where concurrent validity demonstrated I^2 = 97.11%, interrater agreement I^2 = 87.60% and internal consistency I^2 = 90.07%, which therefore indicated a genuine differences underlying the results of the included studies. The high heterogeneity found across all three validity and reliability measures further reiterates the dissimilarity of reported results which can be seen from the funnel plots provided. High heterogeneity has also been reported previously in a meta-analysis which investigated the prevalence of frailty of nursing home residents (Kojima, 2015). Therefore, due to the high heterogeneity across the results, it is not possible to recommend a single most appropriate tool to be used in the future. That being said, the results, even if highly heterogenous, could indicate that the level of validity and reliability in currently used observational pain assessment tool is not as high and uniform as it could be.

Another aspect to consider, is that the studies included in this systematic review typically aimed to validate or evaluate the psychometric properties of observational pain assessment tools, which therefore likely resulted in frequent pain assessment which would have not been completed otherwise. It is thus likely, that the presence and severity of the pain detected in participants would have not been detected and treated appropriately in a setting which was not currently in the process of data collection for a study. This means that the results and heterogeneity from the meta-analysis could have been influenced due to the increased frequency of pain assessment as a result of data collection period, making the results unrepresentative.

Additionally, the majority of the studies included in this systematic review have only focused on specific qualities of the tools. For example, majority of the studies have reported correlation coefficients, such as agreement between multiple assessors, correlations between two or more tools, sensitivity and ability to discriminate between painful and non-painful states. Although these qualities are crucial for observational pain assessment tools, it is also crucial for the tools to be able to discriminate painful behaviours from psychosocial behaviour or distress, or other behaviours which may manifest similarly to pain, such as frustration or anger (Jordan et al., 2011). Hence, it is essential that observational pain assessment tools are able to differentiate between

these states, as the lack of discrimination between them could result in inaccurate assessment of pain and therefore inappropriate amendment of treatment and management plan of pain. Other limitations included lack of cultural differences (Cervo et al., 2009) as participants were predominantly white America, Australian or Caucasian population, and tools were often not validated outside of the country of origin.

Findings by Maxwell et al. (2008) and Nygaard & Jarland (2005) showed under-detection of pain, which consequently results in inappropriate treatment and management of pain. These findings were supported by Monacelli et al. (2013), who demonstrated that pain in people with dementia is often not treated appropriately, in the sense that not all individuals with dementia who need analgesics to manage their pain receive it. This in turn contradicts findings by Haasum et al. (2011) who reported overuse of analgesics in people living with dementia. The findings from the outlined literature and the heterogonous results from this systematic review, raise the question why pain in some individuals is over-treated, while others are under-treated and what role, if any, do observational pain assessment tools play in the variability of treatment received by the individuals in pain. It would also be worth investigating whether correct implementation and frequency of use impacts the findings in this systematic review. For example, a sensitive, valid, reliable and accurate tool which is used sub-optimally or underutilised may produce results which are not truly representative of the tool.

Nonetheless, the studies included in this review were not always explicitly focusing on the use of analgesics, and therefore it is possible that some residents who were taking analgesics were not given the correct dose, meaning that some of the participants could have still been over- or under-treated with analgesics. Unfortunately, this information was not identifiable from the included studies as frequency and dose of administered analgesics were often not reported, which may be a limitation of this systematic review. Furthermore, while Husebo et al. (2007) reported that the majority of participants were already treated with analgesics prior to the start of their study, it was not reported whether the scores from the observational tools have led to alteration any pain management plans or participant's medication.

Additionally, the studies which did indicate an alteration of analgesics following the completion of an observational pain assessment tool, usually reported an increased dose of analgesic medication. However, a higher dose of analgesics might not always be the most appropriate treatment and management method. Therefore, other factors, such as quality of life or activities of daily living, should also be measured as a variable for effective and appropriate pain management plan tailored to each individual (Fine, 2009).

Whitlock et al. (2017) previously reported a relationship between pain and its impact on memory decline, indicating an increased rate of memory decline when pain is present. Unfortunately, due to the main aims of this systematic review, the relationship between pain and memory decline was not investigated directly. However, the findings from Cervo et al. (2012) have shown increased episodes of physically aggressive behaviour (e.g. hitting, biting, kicking), physically nonaggressive behaviour (e.g. hiding objects, pacing) and verbally nonaggressive (e.g. being negative, disliking things). This could potentially suggest a memory and cognition decline, but it is more likely that the behaviours demonstrated by the participants in Cervo's study can be attributed to a decrease of antipsychotic medication. Nonetheless, the possible link between decrease of antipsychotic medication, lower level of pain and increase of distressed behaviour should be investigated further.

The individual articles in this systematic review have reported that the observational pain assessment tools were good at identifying and assessing pain in people with dementia (Jordan, Regnard, O'Brien, & Hughes, 2011; Monacelli et al., 2013; Rat et al., 2011). Yet, these findings are contrary to a significant amount of literature which suggests that pain in people living with dementia is still under-detected (Cunningham et al., 2010), under-treated (McAuliffe et al., 2012) and under-assessed (Royal College of Psychiatrists, 2017). In addition, Sampson, Gould, Lee, & Blanchard (2006) reported that end-of-life care may differ between cognitively intact and cognitively impaired individuals, suggesting inconsistencies not only in treatment in pain, but also care in general. This finding may suggest that the observational pain assessment tools are not accurate enough to detect presence and severity of pain but blaming the tools entirely would not be responsible. Observational pain assessment for people with dementia is complex and assessing presence and severity of pain via the utilisation of

a pain tool is only a small element of the pain process. It could, therefore, also be suggested that observational pain assessment tools are not used appropriately, that the care home staff simply do not have the time to use the tools to their full potential or that other factors, which were not yet investigated, could also be hindering the assessment, treatment and management process. One contributing factor could be the lack of policies and procedures in place for pain management. For example, Allcock, McGarry, & Elkan (2002) found that 69% of care homes did not have a policy for pain management, and 75% of the care homes did not use standardised pain assessment tool. These concerning findings indicate that there is a need for a universal tool which is accurate, reliable but most importantly not underutilised and used sub-optimally. This, however, has not been explored in depth in this review.

Eggermont et al. (2012), have previously published findings stating several factors, including pain can increase the risk of fall in community-dwelling older people. One of the studies included in this systematic review supported these findings, by tracking number of falls in participants over a three-year period (Cervo et al., 2012). Although the reported results were not statistically significant, the study has demonstrated a large reduction of falls with an effective pain management strategy for individuals with dementia. Previous research indicated a positive correlation between the number of falls and pain in older population (Blyth, Cumming, Mitchell, & Wang, 2007; Leveille et al., 2009). This was supported by Cervo et al. (2012), who demonstrated a decrease of falls in care home residents after the observational pain assessment tool CPAT was implemented to enhance pain management and treatment. However, the information about the number of falls in Cervo et al (2007) study was obtained from accident and incident book, and therefore there is a possibility that the falls were not directly associated with pain.

Additionally, the systematic review also investigated the pain domains included across the eighteen identified observational pain assessment tools. Despite the American Geriatrics Society (AGS) strongly recommending the use of all six pain domains for an effective and more accurate observational pain assessment (AGS, 2002) this review found that only two tools included all six pain domains as part of the pain assessment. The lack of implementation of all six pain domain across observational pain assessment tools could explain the heterogeneity of the results and the inconsistency

of reported accuracy for detection of presence and severity of pain in people with dementia. Therefore, it could be suggested that the inclusion of all six pain domains in all observational pain assessment tools could increase overall accuracy, validity and reliability of pain assessment.

4.4.1 Strengths and limitations

The findings from this systematic review may be able to explain the inconsistencies in reported accuracy and reliability of pain assessment tools, through the heterogeneity of data. As mentioned above, the heterogeneity of results highlights the presented issue regarding poor management and treatment of pain in people living with dementia and reiterates the need to further develop or enhance pain detection and accuracy measures. Many of the observational pain assessment tools outlined in this review, did not include all of the domains recommended by the AGS, which could partially explain some of the heterogeneity of results and poor accuracy of tools. Especially considering that one of the most popular and widely used observational pain assessment tool; the Abbey Pain Scale (Abbey et al., 2004) does incorporate all six domains into the assessment.

This research strengthens and adds to already existing knowledge, by providing further evidence that most of the current observational pain assessment tools continue to demonstrate inconsistent results when the validity and reliability measures are compared. Additionally, the narrative element of this review suggested an explanation for this inconsistency within reliability and validity measures and indicated a solution to strengthen the accuracy of observational pain assessment tools in the future. Part of the discussion should also mention whether this systematic review could have recommended a single observational pain assessment tool for future use. It should be noted that the aim of this review was not to recommend a single tool, but instead to highlight some of the elements of observational pain assessment tools which may contribute to why pain is still commonly mistreated in people living with dementia today. The author acknowledges that this issue is far more complex than an

investigation and comparison of psychometric properties in terms of validity, reliability and accuracy could suggest, and as such it is difficult to use the findings from this review to be able to responsibly make a recommendation or a suggestion.

However, limitations of this systematic review were noted. Firstly, not all observational pain assessment tools have been identified in the database search phase of this systematic review. It has been acknowledged that observational pain assessment tools such as Discomfort Scale for Dementia of the Alzheimer's Type (DS-DAT) developed by Hurley et al., (1992), or the Face, Legs, Activity, Cry, Consolability (FLACC) developed by Merkel, Voepel-Lewis, & Malviya (2002) or even the Abbey Pain Scale (Abbey et al., 2004) have not been included. There could be multiple possible explanations for this; it is possible that the search strategy was not comprehensive or sensitive enough, or that the inclusion and exclusion criteria were too strict. This could potentially be explained by the databases included in the search strategy. Although it included majority of health and psychology-based databases and indexes, it did not include Embase, Cochrane Library and other health and geriatric based databases. The databases and indexes which were perceived as the most appropriate for this topic were included, however wider range of databases could have led to the discovery of additional journal articles.

In addition, the author acknowledges that the range of focus and questions which this systematic review set to answer were narrow in terms of the research questions and psychometric qualities which have been investigated. This was deliberate, as the findings from this systematic review helped to directly inform the results in the validation study in Chapter 6. Aspects, such as psychometric properties were therefore investigated in depth and as such the inclusion and exclusion criteria were design to include studies which were similar to the validation study. For this reason, only studies which compared two or more observational pain assessment tools met the inclusion criteria. Moreover, it has also been acknowledged that restricting the systematic review and only focusing on very specific elements, such as psychometric properties, could have hindered the overall results of the review. However, it should also be noted that this information was deemed as directly relevant to the rest of the PhD project. Therefore, future research should focus to further investigate the aspects which were

not covered within this review, to gain a further insight into some of the challenges assessors are currently facing.

Another identified limitation is that the majority of the observational pain assessment tools used in the studies were completed by highly skilled, experienced and trained nurses. It is highly likely that the nurses were very familiar and able to differentiate a participant's painful and non-painful behaviour, and therefore tested their own knowledge of the participant rather than the observational pain assessment tool itself. While it is crucial that the user of the observational pain assessment tools is familiar with a pain-free behaviour of the participant and training is provided, some subjectivity and human bias could, as outlined in Chapter 2, could have hindered the overall validity and reliability results.

4.5 Conclusion

In conclusion, while the individual studies tend to state that the observational pain assessment tools which were validated or evaluated are accurate, reliable and an appropriate tool to be used in practice, the findings in this systematic review did not support that. The reported validity and reliability results across the studies seem to vary significantly, resulting in a heterogeneous meta-analysis, which could explain why identification, treatment and management of pain in people with dementia is still a major issue.

Therefore, future research should aim to investigate factors which negatively impact the identification and management of pain in older people, and focus on enhancing accuracy, validity and reliability of observational pain assessment tools by either including all six pain domains recommended by the AGS, or reducing factors which hinder accurate assessment. In addition to this, it would be useful to also conduct a study which includes a wider range of questions and has wider inclusion criteria. For example, further investigation into treatment utility of assessment, the appropriateness of tool development processes, content validity, training and others. This may result in

a review of studies that focus on adequacy, practical usefulness and other aspects of observational pain assessment tools.

The results above indicate that there is still a need for a more accurate and reliable pain assessment tool, which further improves on the strengths and limits the weaknesses of current pain assessment tools. Such tool could not only help a better approach and understanding of pain overall, but more importantly can prevent our loved ones from dying in pain.

5 Chapter Five - Qualitative study

5.1 Introduction

Older people living with dementia often experience pain due to chronic conditions such as osteoarthritis or arthritis (Balfour & O'Rourke, 2003). As outlined in the literature review (Chapter 2) and the systematic review (Chapter 3), pain in people with dementia is often poorly managed (Lichtner et al., 2016) as a result of misinterpretation and inaccurate pain recognition and assessment (Mcauliffe et al., 2008). The presence of pain in older people co-exists with behaviours such as agitation, increased stress, aggression and even depression (Manfredi et al., 2003), which make approaching the individual a risk factor. In addition, stress, which may be caused by the presence of pain, can negatively affect quality of life. This was investigated by Sakamoto, Ando, & Tsutou (2013), who found that a music intervention decreased stressed in individuals with severe dementia which in turn improved quality of life. The results from Sakamoto et al. (2013) study reiterate the importance of correctly assessed, treated and managed pain, which can lead to reduced stress and therefore increased quality of life in people with dementia.

When self-report of pain is no longer an appropriate way to assess pain, observational pain assessment tools are completed to understand the presence and severity of pain. For example, some of the observational pain assessment tools currently used across the world to help health professional across a variety of settings recognise and assess pain in people with advanced dementia are; Abbey Pain Scale, Pain Assessment in Advanced Dementia (PAINAD), Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN). While observational pain assessment tools are currently the only alternative to self-report pain measures, research has demonstrated some limitations such as underestimation of pain, bias of assessor (Prkachin et al., 2007), and even unconscious racial bias (Kaseweter et al., 2012).

The number of studies which focus on the development, validation, evaluation of psychometric properties and translation of already existing observational pain assessment tools is vast. However, it has been noted that the main focus in these studies tends to be on evaluating psychometric properties, specifically reporting validity and reliability of tools, rather than feasibility. The definition and use of the term feasibility has previously been discussed and questioned. Arain, Campbell, Cooper, & Lancaster (2010) built upon a previous review conducted by Lancaster, Dodd, & Williamson (2004) where the term "feasibility" has been discussed. Arain et al. (2010) reviewed 54 studies, which were classified by the authors as either "feasibility" studies or "pilot" studies. The findings of the review suggested that the term "pilot" is often used in studies which have developed a much more rigorous design compared to "feasibility" studies, however "pilot" and "feasibility" studies are still inappropriately reported in retrospect to their chosen "pilot" or "feasibility" design. In addition, the National Institute for Health Research Evaluation Trials and Studies Coordinating Centre (NETSCC) suggests that "feasibility" studies should be conducted prior to main studies, to help researchers estimate the important parameters needed to design the main study (NETSCC, 2018).

Because of the continuous debates and some inappropriateness of the use of the term "feasibility" (Arain et al., 2010) in the past, this study will define the term feasibility and the appropriateness of its use in this context. This study is not a "feasibility" study as defined by the NETSCC, but instead aims to explore the views of whether PainChek® a newly developed semi-automated electronic pain assessment tools, is perceived as being feasible from the perspective of participants (nurses, care home staff and allied health professionals). Therefore, the questions in the interviews were designed to focus on the ease of use and convenience or lack thereof, of observational pain assessment tools in care homes. Therefore, in this study feasibility refers to a tool's "applicability in daily practice, including aspects such as ease of use and time to administer it" (Lichtner et al., 2014, p.14). In the context as defined by Lichtner et al. (2014), feasibility for observational pain assessment tools has been explored and evaluated, to ensure its applicability and suitability for clinical and daily practice.

Zwakhalen, Hamers, Peijnenburg, & Berger (2007) noticed that there was a lack of research focusing on nurses' knowledge and beliefs about pain in individuals with

dementia. The lack of research and understanding in this area could be one of the reasons why pain assessment in people with dementia is poor (Peisah et al., 2014) and prone to subjective bias. Scales to measure knowledge of care home staff regarding pain, such as the Pain in Older Adults Knowledge Survey (POAKS) (Fetherstonhaugh, Lewis, McAuliffe, & Bauer, 2016), have therefore been developed. POAKS is not a dementia-specific scale, instead it is a general scale which focuses on pain in the older people, and therefore it can be applied across a variety of nursing settings with older adults as patients. In the original validation study (Fetherstonhaugh et al., 2016), POAKS was completed by three groups of participants; first-year nursing students, third-year nursing students and residential aged care staff. The results have shown that on average the first-year nursing students have scored the lowest on the POAKS scale (mean score 15.9) and therefore demonstrating the least knowledge about pain in older adults. This was followed by residential aged care staff (mean score 18.4) with third-year nursing students scoring the highest (mean score 19), indicating that there may be an experiential element to pain assessment in health care professionals.

Martin, Williams, Hadjistavropoulos, Hadjistavropoulos, & Maclean (2005) explored the concerns and challenges of pain assessment and management from care recipients such as older people experiencing pain, informal caregivers and health professionals. While the concerns and challenges were mostly related to self-report pain assessment, it was interesting to note that the majority of the focus groups in this study suggested that older people adults might have difficulty describing the severity of the pain they are experiencing to health professionals, however the reasons behind this were not reported. Nevertheless, another identified theme in the study by Martin et al (2005), focused on reasons for underreporting of pain by the older people. The participants have noted that reasons such as stoicism or not wanting to bother others could be some of the reasons behind underreported pain in the older people.

Additionally, the focus groups also reported concerns about subjectivity of pain assessment and the individual differences of how pain can be expressed across individuals. Additionally, Liu (2013) explored nursing assistants' roles during assessment, reporting, implementation of pain relief intervention and re-assessment tasks. Liu's (2013) study highlighted the importance of the level of familiarity with

patients during an observational pain assessment, with the participants confirming that prior to a formal assessment of pain, the initial suspicion of presence of pain is usually identified by noting changes to daily behaviour in the residents. This, therefore, requires a higher level of familiarity of the resident and prior knowledge of the resident's typical behaviour.

Pautex et al. (2005) conducted a study which aimed to investigate the feasibility and reliability of four self-report pain assessment scales. While the authors state that feasibility and reliability of four observational pain assessment scales were addressed, the authors did not state how feasibility was measured, or what the outcomes were for the four scales, which is a major limitation of the study. Additionally, a study by Zwakhalen, van't Hof, & Hamers (2012) also aimed the investigate the feasibility of observational pain assessment tools, specifically the Dutch version of Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC-D). Zwakhalen et al. (2012) investigated perceived feasibility by conducting structured interviews with the nursing staff. The interviews were structured to explore several aspects of pain assessment, including gaining insight into pain policies, pain situations and experiences on feasibility and acceptability of pain assessment tools. The analysis of the interviews has demonstrated that some interview participants evaluated the PACSLAC-D as user-friendly and feasible, however no further information about which elements were user-friendly was provided.

Research into views and opinions regarding feasibility of observational pain assessment tools is very limited. When feasibility is reported (appropriately or inappropriately as previously suggested by Arain et al. (2010), it typically focuses either on self-report pain assessment measures, or on a preliminary study, which is conducted prior to a main study. Lichtner et al. (2014) conducted an exploratory systematic review of systematic reviews and has identified that in many observational pain assessment research studies feasibility data were either absent or have stated feasibility without supporting evidence. Feasibility should, therefore, be explored and reported for all observational pain assessment tools available and especially those which are newly developed, as it would enhance transparent reporting and suggestive evidence of potential use and implementation of interventions for everyday practice.

Due to the limited qualitative research on perceived feasibility of observational pain assessment tools, this qualitative study aims to gain insight by investigating strengths and limitations of the Abbey Pain Scale and the PainChek®. Hence, feasibility was explored by investigating views about the Abbey Pain Scale and the PainChek®, of care home staff who were likely to use observational pain assessment tools on regular basis. The qualitative investigation helped to develop understanding of any perceived challenges, limitations and strengths which individuals with previous experience of working in the care home have highlighted.

The aim of the qualitative study was to explore feasibility in terms of views and opinions of care home staff and allied health professionals of PainChek® and Abbey Pain Scale.

The objectives were:

a) To explore views and opinions regarding the PainChek® and the Abbey Pain Scale with care home staff and allied health professionals using semi-structured interviews
b) To investigate common themes and sub-themes regarding the feasibility of PainChek® and Abbey Pain Scale in terms of perceived strengths and limitations using a thematic analysis technique
c) To briefly explore participant level of knowledge regarding pain in the older people using the Pain in Older Adults Knowledge Survey (POAKS)

Please note that PainChek® was called ePAT at the time of data collection in 2017, therefore the transcripts will often refer to PainChek® as ePAT.

5.2 Methodology

5.2.1 Design

The present exploratory descriptive study has taken a qualitative inductive approach on a semantic level to conduct semi-structured interviews. A constructionist epistemological approach was adopted in recognition that knowledge is constructed through convention, human perception, social experience and its pragmatic stance, thus giving the researcher some flexibility in the analysis of the transcripts and data on a more descriptive level. The constructionist epistemology was difficult to apply to the PainChek® element of the interviews, due to the lack of previous experience and exposure the participants had to PainChek®. Therefore, the researcher has adopted more of a semantic and exploratory approach to explore key identified strengths and limitations highlighted by the participants. The Abbey Pain Scale and PainChek® were selected for the semi-structured interviews for the following reasons: firstly, the APS and PainChek® are similar in terms of the pain domains both tools utilise. Secondly, the participants recruited from the care homes all had experience using the APS, which helped to discuss its strengths and weaknesses of this tool. Finally, these two tools are also directly compared in the Validation of PainChek® study (Chapter 6), therefore exploring any strengths and weaknesses of the PainChek® prior to further validation in the UK and potential implementation in the future was useful.

Semi-structured interviews were used to collect data from participants. Semi-structured interviews are often used in healthcare by professionals in their research areas (Jamshed, 2014). The main aim of semi-structured interviews is to gather information from participants regarding personal attitudes, perceptions and beliefs to the topic of interest (DeJonckheere & Vaughn, 2019), and it allows the researcher and the participant to talk about opinions on a particular subject in more detail.

Thematic analysis (Braun & Clarke, 2006) was used to identify common overarching themes and subthemes across the transcript. Braun & Clarke's (2006) six-step phase guide was used to carry out the thematic analysis. The six-steps were; 1.

familiarisation, 2. generating initial codes, 3. searching for themes, 4. reviewing themes, 5. defining and naming themes and 6. producing the report. Saturation was reached when no new topics were mentioned in the interviews.

The data collected during the interviews were transcribed and are presented verbatim in this chapter. Ethical approval was granted by the College Research Ethics Committee, College of Health and Social Care at the University of Derby (see appendix 5.1).

5.2.2 Participants

Ten participants were recruited from two UK based care homes in an urban setting. All participants had an experience or were working at dementia specialised nursing homes with a CQC rating of “outstanding” and “good” at the time of data collection. The two dementia specialised nursing home had a capacity of 89 and 50. Participants were recruited using convenience sampling. The demographic information about the participants is shown in Table 5.1.

Table 5.1. Participant’s demographic information and POAKS scores

Mean age (SD), years	40.0 (14.19)
Median age (range), years	38.5 (20-62)
Gender, N (%)	
Male	2 (20)
Female	8 (80)
Ethnicity, N (%)	
White British	8 (80)
Asian	2 (20)
Mean POAKS score, (SD)	20.4 (1.71)
Median POAKS (range)	20.0 (17-23)
Role within the care home, N (%)	
Lead nurse (inc. team leader or manager)	3 (30)

Carer	2 (20)
Care Assistant	2 (20)
Registered nurse	1 (10)
Allied Health Professional	1 (10)
Resisted nursing associate	1 (10)

5.2.3 Materials

The following five materials were used to complete the qualitative study:

1. A scale to assess and gauge participants' knowledge of pain in the older people was assessed using the POAKS scale (Fetherstonhaugh et al., 2016). POAKS provides 24 statements about pain in the older people population, which the participants score as "true", "false" or "don't know". The POAKS scale is scored on a 0-24 points basis, where higher scores indicate better knowledge about pain in the older people.

2. NVivo12 is a software which was used in the coding process of the data analysis. NVivo enables the researcher to identify and code themes electronically, and store them into categories and sub-categories. This process is very similar to the usual coding process, and therefore does not take away from the immersion process during coding of themes and sub-themes.

3. To comply with the General Data Protection Regulations (GDPR) (GDPR, 2018), all interviews were recorded using a recorder. The recording files were transferred to a password-protected folder and deleted from the recorder.

4. A two-minute PainChek® video was shown to the participants when they were introduced to PainChek®. This video was publicly available on the PainChek® website at the time of interviews.

5. Lastly, each participant, regardless of their familiarity and precious experience, was given a copy of the APS during the interviews. This allowed the participants to pinpoint specific aspects of the scale, and talk more specifically about the domains or the tool's aspects.

5.2.4 Procedure

The researcher approached potential participants such as nurses, nursing associates, other care home staff and visiting allied health professionals. Information about the study in form of an invitation to participate letter and participation information sheet were given to all potential participants. In addition to approaching potential participants in person at the care home, the invitations to participate and participant information sheets were distributed across the care home's staff only areas, such as staff rooms, to increase the likelihood of recruitment. The permission to do so was given by the managers of the care home.

Most appropriate and convenient times to conduct interviews were discussed with managers and lead nurses on shift prior to conducting interviews, to ensure that enough staff were available to continue completing daily tasks without feeling pressures of being understaffed. Participants who were interested to take part in the study were able to either contact the researcher directly using the contact information provided on the participant sheets (see appendix 5.2) or approach the researcher during times when the researcher was visiting and observing at the care home.

Once participants have agreed to take part in the study, they have been given an opportunity to ask any questions regarding the study. The researcher has then asked the participant to sign a consent form. First, the participants have been asked to fill out the 24-item POAKS questionnaire to assess their knowledge of pain in the older people. This score was also used as an analysis of overall knowledge of pain in the older people across the participants. After the participants filled in the POAKS questionnaire, the interviews have commenced. The first part of the study focused on

currently used observational pain assessment tools, specifically the Abbey Pain Scale (APS).

Questions regarding the feasibility of the scale, specifically in regards to its use, strengths and limitations were asked. Majority of participants were familiar and have had an experience with using the APS in the past. However, if this was not the case, the participant was introduced to the APS. During the introduction of the APS, the participants were given a brief explanation about how the APS is used and were given a copy to study for a few minutes, so that they were able to answer the questions in the interviews. The participants who were familiar with the APS have been provided with a copy to refer to when needed during the interviews.

Once all questions about APS have been asked, the second part of the interview commenced. This part of the interview focused on perceived feasibility, perceived strengths and limitations of the PainChek®. It was very unlikely that the participants would have heard of the PainChek® in the past, as at the time it was not available for clinical use. Therefore, prior to asking the questions, all participants have been introduced to PainChek®. This was achieved by showing participants a two-minute long video, which at the time was publicly available on the website. Once the participants watched the video, the researcher then started asking interview questions. The order of the interview parts was not counterbalanced, therefore the participants always answered questions about the APS first, followed by the PainChek®. This was done to prevent bias towards the APS when compared to the PainChek® and its novelty semi-automated facial recognition feature.

5.3 Analysis

Due to the nature of this study, the semi-structured interview questions were designed to focus on feasibility, perceived strengths and perceived limitations of the APS and the PainChek®. Because of this, the analysis is broken down into five sections; perceived strengths of APS, perceived limitations of APS, perceived strengths of

PainChek® and perceived limitations of PainChek®. This hybrid strategy of thematic analysis by strengths and limitations and inductive identification of sub-themes generate from the data, allowed the researcher to explore specific elements of feasibility, in this case, perceived strengths and limitations. Additionally, the participants were encouraged to talk about any previous experiences which were related to pain assessment. The analysis of the extracts identified additional themes and sub-themes which were related to assessing pain in the care home. The additionally identified main theme was labelled “critical factors of pain assessment2. Each section was then broken down into themes and sub-themes (see table 5.2).

Table 5.2. Identified themes and sub-themes

Name of themes	Name of sub-themes
Theme 1: Limitations of APS	Sub-theme 1: Restriction Sub-theme 2: Time consumption
Theme 2: Strengths of APS	Sub-theme 1: Facial expression domain
Theme 3: Limitations of PainChek®	Sub-theme 1: Using a phone in a care home Sub-theme 2: Putting on a persona
Theme 4: Strengths of PainChek®	Sub-theme 1: Automated facial recognition Sub-theme 2: Decreased time consumption
Theme 5: Critical factors of pain assessment	Sub-theme 1: Subjectivity of pain

	Sub-theme 2: Familiarity with residents
	Sub-theme 3: Challenging perceptions of pain and dementia

5.3.1 Theme 1: Perceived limitations of the Abbey Pain Scale

The first section, which was of interest as part of exploring perceived feasibility of the Abbey Pain Scale was the perceived limitations. The participants mostly expressed their concerns in terms of its restrictiveness and the amount of time it takes.

5.3.1.1 Sub-theme 1: Restriction

Several participants have pointed out the Abbey Pain Scale can be restrictive in terms of assessing a person in a holistic manner. For example:

> *"it limits you to look at the person as a whole.. you're looking at a certain aspect but then it's almost once that box is ticked and you are finished then you automatically see that your assessment is complete"*

The participant pointed out that the pain assessment did not necessarily go beyond the assessment (i.e. continuing to provide holistic care approach once the assessment is completed), which potentially restricts how the individual in pain is cared for and how their pain is perceived. Additionally, participants highlighted the restrictions and limiting aspects of the Abbey Pain Scale in terms of the range of the scoring system and the pain presence and severity categories.

“I think these categories [points to Abbey Pain Scale] can be a little bit limited having that small range, you know? “

The participant in the above quote was referring to the scoring system for each pain domain in the Abbey Pain Scale. The scoring system for each domain the Abbey Pain Scale works on a scale of 0-3, where 0 represents an absence of specific pain behaviour, 1 represents mild, 2 moderate and 3 severe presence of specific pain behaviour. This notion that the scoring system can be biased and subjective, and will vary based on personal past experiences is explored in more detail as part of theme 5, sub-theme 1 in this chapter.

Another participant also had similar views:

“ I think it’s a little bit restrictive in a way.. it’s like… the score whatever you score is relates to how severe it is.. things like facial expression some people might not show on their face their pain and lost points with that and that kind of thing…”

This sub-theme could be vaguely linked to the Capability element of the COM-B model. The participants here have pointed out that the restrictive scoring system of the APS could hinder the accuracy and reliability of observational pain assessment. The Capability element of the COM-B approach suggests that behaviour can be changed if an individual perceives that they have a psychological or physical ability to enact the behaviour. Therefore, if participants have the belief that they are capable of completing the observational assessment more accurately by utilising the tool, this could be the first step to increasing frequency of use of the tools.

5.3.1.2 Sub-theme 2: Time consumption

The second sub-theme regarding the limitations of the Abbey Pain Scale concerned the completion time. The concerns expressed regarding the amount of time it takes to complete the Abbey Pain Scale mostly referred to the observation required prior to completing an assessment or during the completion of the assessment. This most likely directly referred to the previously reported barrier to good dementia-care due to lack of time and staffing (Fessey, 2007).

> *"its quite time consuming, but, the idea of it is good"*

> *"if they're downstairs and they have injured themselves and they're gonna get really agitated aren't they, they're not gonna want to sit with you for ten minutes while you… while you assess their scale "*

This sub-theme could also be linked to the Capability element of the COM-B approach. This time, the perceived physical inability to complete a scale due to lack of time as a result of workload may be hindering the initial step needed for behaviour change. In addition, the Opportunity element could also be applied within this sub-theme. The opportunity element consider the physical and social environment that enables the behaviour change. In this case, the physical environment (care home or a nursing home) may not enable the behaviour of utilising an observational pain assessment tool due to the time it takes to complete the form, which the care home staff may not have due to the workload they are faced with.

5.3.2 Theme 2: Perceived strengths of the Abbey Pain Scale

On reflection of the strengths of the Abbey Pain Scale, the majority of individuals highlighted the importance and strengths of incorporating facial expression into an observational pain assessment, as they perceived that individuals with dementia would likely express their pain most clearly through their facial expression.

5.3.2.1 Sub-theme 1: Facial expression domain

Participants identified that from their experience of working in a care home setting, pain can usually be identified by looking at the person's face first.

> *"I think facial expression probably always comes first doesn't it cause you can always tell by the face…"*

> *"obviously if they're not able to communicate you're looking for facial signs"*

> *"especially in dementia clients because they can't always tell you you know if they do tell you you have facial expression"*

The three participants all identified the importance of initially assessing and looking out for changes in facial expression. They state that the signs of pain are most easily identifiable from the facial expression and therefore the facial expression pain domain category within the Abbey Pain Scale is the most useful.

> *"your facial expressions would be the first thing you see obviously and then of course if they're not happy you gonna get the expressions through the behaviour so"*

“ and body language I think that tells quite a lot… The vocalisation not everyone would be noisy while in pain. Sometimes people tense up”

In terms of the strengths of the Abbey Pain Scale, no other aspects or elements of the tool were mentioned, apart from specific pain domains or the description within the pain domains. For example, participants have highlighted that the examples provided within each pain category were a helpful guideline to identify which behaviours to look for (i.e. in the vocalisation pain domain, the Abbey pain scale gives the following examples of behaviours; whimpering, groaning crying). Participants were also highlighting the facial expression domain and the associated behaviour domain as the most important and therefore the strongest element of the Abbey Pain Scale.

Linking this back to the COM-B model, it would be interesting to explore how the capability element links in with the facial expression. As outlined in the extracts above, participants stated that they were capable of identifying whether a person is in pain simply by looking at their facial expression. This is an important aspect and one of the first steps of pain assessment, which could lead towards the desired behaviour, which is increased frequency of the utilisation of an observational pain assessment tool.

5.3.3 Theme 3: Perceived limitations of PainChek®

The next section, which the interviews focused on, were related to PainChek®. The discussion surrounding PainChek® were somewhat less descriptive, and participants were unable to talk about any previous experiences with this PainChek® because at the time of the data collection for this study, PainChek® was not widely available for clinical use in the UK. The participants were encouraged to relate their previous experience and expertise in using other pain assessment tools where appropriate during this interview.

Due to the partial overlap of study data collection period, some participants might have seen the researcher use the PainChek® within the care home during the data collection period for the Validation of PainChek® study.

The two reoccurring sub-themes in this part of the interview were concerns expressed surrounding using an electronic phone device within a professional setting and the reaction from the residents to the device.

5.3.3.1 Sub-theme 1: Using a phone device in a care home

When participants were asked about their perceived limitations of the PainChek®, one of the main concerns was about the professionalism, or lack thereof, of using a mobile device within a care home.

> *"yeah they're [relatives of residents] coming to visit and they see you using a mobile phone but not realising what you're using it for but you'd be able to explain that to them wouldn't you"*

> *" to be seen as a care team with your mobile phone out gives a negative impression"*

Some participants were also concerned about how the residents will respond to the device, especially as they might not be familiar with a mobile phone device, or a device that is bigger such as a tablet.

"An older person might not be as familiar with phones and things like that… they might think that you're taking photographs and if they're confused then it might upset them"

However, all these concerns were appraised as fairly minor and they would not impact on the likelihood of the nurses using the PainChek®. Participants also pointed out that explanation of why and how PainChek® is being implemented and used through a mobile phone or a tablet device would be sufficient to justify its use to visiting relatives and some residents too.

This sub-theme could be linked back to the Motivation element of the COM-B model. The Motivation element suggests that behaviours can be activated or inhibited by reflective or automatic mechanisms. In this case, the participants mentioned that using a mobile device in a care home setting may be seen as unprofessional by relatives of the residents or other visitors. This may inhibit the behaviour of using an electronic pain assessment tool on regular basis, rather than activate it.

5.3.3.2 Sub-theme 2: Putting on a persona

The second common sub-theme focused on how the behaviour of residents can change when an electronic device such as a phone or a tablet device is used. The PainChek® incorporates an automated facial expression feature which uses the camera on the device to scan a face and identify presence of specific facial features which are indicative of pain.

Putting on a persona was identified on two levels. The first looks at how the residents reacted to the researcher when approached. In other words, some residents consciously or unconsciously altered their painful behaviour when approached by a person who they were not too familiar with. For example, outlined in the quote below, the participant talked about how some residents masked their painful facial

expression, vocalisation and some physical behaviours when the researcher approached them during the familiarisation and visiting stage. For example, during regular visits, the researcher spent time with the staff of the care home but also many of the residents. To begin with, the residents would mask their painful behaviours, as they often reacted differently to the researcher compared to care home staff. It became apparent that when a resident was approached by the researcher, who during the first few weeks was perceived as a stranger, the residents were likely to smile as soon as they were approached rather than express their true pain behaviour, thus masking their pain behaviour. This concept is further discussed in the case study chapter (Chapter 7).

> *" it was interesting to identify that because people are familiar to me [a member of staff in the care home] or the person that they know from… for a while therefore it could affect some of the results initially… which we established early on but then once somebody else is then approached that pain can't be masked…"*

The second level of the putting on a persona sub-theme is how the residents reacted to the device on which the PainChek® scores were collected. In the two care homes were the researcher collected the interview data from, both care homes often took pictures of the residents to send to the relatives if requested. This often meant that the residents thought a picture was being taken, when the researcher tried to use the automated facial feature function of PainChek®.

> *"people will pull a different face take their glasses off, they will present themselves in a manner that they think people wish to see them so therefore they are then masking the reason that the device is being used for.. "*

> “people automatically presume that if we’re holding up something that they must smile for it like it’s an old fashioned camera so it’s just bringing their attention to you but not directly to the device that we’re using”

Because some residents thought a picture was being taken, their facial expression which was indicative of pain was often suppressed for a short period of time while the resident thought the picture was taken. This sub-theme does not link to any of the COM-B elements directly, however, it demonstrates the care home staff’s understanding of different behaviours which can be expressed by the residents during different situations.

5.3.4 Theme 4: Perceived strengths of PainChek®

Although some participants have seen PainChek® being used at the care home during the data collection for Validation of PainChek® study, it was unsurprising that the majority of the participants highlighted the automated facial recognition feature as strength of PainChek®. The automated facial recognition feature is a novelty element in observational pain assessment and the video which has been shown to the participants also demonstrated how the algorithms of the facial feature recognition work. Because of this, the major overarching sub-theme was the facial expression feature, with the second most common sub-theme focusing on decreased time consumption when using the PainChek® to assess pain.

5.3.4.1 Sub-theme 1: Automated facial recognition feature

Participants often highlighted that the use of an automated feature which is built into an observational pain assessment can help reduce subjectivity and help assess pain in people which the care home staff are not as familiar with.

> *"if you're not familiar with somebody, you might not know how they express pain whereas the app might be better for picking that up"*

> *"we fill in these scales but it's only an opinion of what their face is whereas on something like that [ePAT] it's a lot more certified"*

> *"I think anything that takes the subjectivity out of an assessment is good.."*

In addition to identifying that eliminating or reducing subjectivity is a strength of the PainChek®, some participants also highlighted that the reduced subjectivity would increase accuracy of the tool.

> *"probably has some strengths to it to be honest might be more accurate because some people would just give out analgesia for the sake of giving it which sometimes they probably don't need it"*

> *"think a phone would be quicker than using paper so you could do your job effectively not so much as quicker but you can do it effectively and maybe score it better"*

Some participants liked that the subjective element of the pain assessment is still present, but the objective automated facial recognition is incorporated. That way the person who is using the PainChek® to assess a resident in a care home still has to use their own expertise and assess based on their previous knowledge and familiarity with the residents' behaviours.

> *"I suspect that it would be slightly more accurate because it's your subjective opinion and also having an objective extra on top that's reading the face itself"*

Again, capability and opportunity from the COM-B model could be linked here. The participants have shown that the PainChek® could enhance the capability of the assessor to detect pain, which may in turn increase the frequency of use of observational pain assessment tools. In addition, the participants have also recognised that there is an opportunity to use an electronic tool within a care home setting, stating that using an app, rather than a paper passed version, could speed up the pain assessment process.

5.3.4.2 Sub-theme 2: Decreased time consumption

The second sub-theme identified focused on the amount of time it takes to administer the PainChek® compared to the Abbey Pain Scale to assess pain. This sub-theme was very interesting to identify for a couple of reasons. Firstly, participants have previously highlighted the length of observation as a negative feature of the Abbey Pain Scale, and secondly the participants have never used the PainChek® in practice before, therefore they could not have been certain of its practicality and feasibility. Yet, time as a sub-theme reoccurred throughout the interviews.

"I think it's a good idea and I think it'll prob….mmm.. i.. actually… on a time scale it would take up any less time than it would to fill in the sheet"

"like if it's on the phone or a pad or whatever it's on, you can keep it on you at all times can you so if some… something was to happen, you can get it out and use it straight away whereas on paper is.. sounds silly but it's things like having to find a pen having to find that paper and get to them [the residents] in time before… they're in too much pain really"

The ease of accessibility to a mobile phone device or an electronic device has also been highlighted in the quote above, which is perceived as a strength of using the PainChek®. Hence, despite the participants not using the PainChek® before, they identified that being able to assess pain electronically would take less time than when the assessment is recorded with a pen on paper. In addition, this sub-theme could be linked to either opportunity or motivation of the COM-B model. Opportunity, in terms of recognising how an electronic observational pain assessment tool would fit in within a care home setting, and motivation in terms of acknowledging that a tool like PainChek® could decrease the time needed to assess an individual in pain.

5.3.5 Theme 5: Critical factors of pain assessment

In the final theme, participants often talked about pain as a subjective experience, the importance of familiarity of care home residents and they also challenged some stigma associated with pain and dementia.

5.3.5.1 Sub-theme 1: Subjectivity in pain

The first sub-theme which was identified focuses on how subjectivity is understood and perceived when assessing pain in people who are unable to communicate it, such

as people with dementia. Some participants recognised the potential difficulty with pain being experienced differently by individuals (i.e. due to pain thresholds, previous experiences of pain and the variety of expressed pain behaviours), and how this can affect the accuracy of pain assessment.

> *"it's difficult because my three pain isn't the same as your three pain… so therefore to put it on a scale comparing my results to your results they might differ"*

> *"I think it would be very tricky to use to begin with… because just of a lack of experience and how subjective a lot of the categories are [talking about pain domains in general]"*

The participants in the quotes above recognise how pain assessment results may vary from assessor to assessor, in terms of potential bias and human error. This is an important factor to recognise, especially in a care home setting where pain can be assessed by different care home staff or nurses, depending on the shift schedule and time rota. While nurses are allocated to take responsibility for certain residents within the care home, if pain needs to be assessed and the allocated nurse is not present, other nurses are likely to complete the pain assessment scale, which might therefore result in a different pain score overall.

> *"So I think the physiological changes you can rely on just based on numbers.. but it could be.. what somebody says is mild compared to moderate vocalisations and facial expressions is very subjective"*

“we are aware of the pain that people are in but not necessarily on what level they’re experiencing it”

Other participants preferred the physiological changes as a pain domain, because they were easier to identify. For example, in the physiological changes domain of the Abbey Pain Scale, the assessor is required to consider symptoms which are easier to identify or test such as changes in pulse or blood pressure or changes in body temperature.

In a similar way to previous sub-themes, this sub-theme could also be linked back to the capability element of the COM-B model. In a way, the participants may have been questioning whether the observational pain assessment tools are capable enough to enable the care home staff to accurately and reliably detect presence and severity of pain in people living with dementia. A belief that the staff have the ability to accurately detect pain might enhance the frequency of the use of pain tools.

5.3.5.2 Sub-theme 2: The importance of familiarity with residents

The second identified sub-theme was the importance of being familiar with a pain-free behaviour of care home residents. The participants often highlighted that being familiar with the residents’ pain-free and painful behaviours helps them identify pain more accurately.

“The way they move the way they.. how they react if they are in pain I think I can manage to assess.. but I need to know first the residents before.. not first day of going there and then.. yeah… I need to… few days maybe”

“most of them [painful behaviours] are so familiar because we see them daily and their individual families…”

The familiarity of residents, in terms of having experience of the person with dementia and their painful or pain-free behaviour, is recommended by most observational pain assessment tool. The observation and subsequent completion of an observational pain assessment tool such as the Abbey Pain Scale is more accurate when the assessor is familiar with the resident which they are assessing. This could be linked back to the motivation element of the COM-B approach. Being familiar with the residents' pain-free and painful behaviours could be the reflective and automatic mechanisms that activate or inhibit the behaviour of using an observational pain assessment tool. If the care home staff detect behaviour which they think could be expressing pain, this could ether activate the behaviour of using a pain tool because the member of staff might want to establish assess the presence and severity of pain, or hinder the behaviour if the member of staff thinks that they are familiar with the behaviour enough not to use the observational pain assessment tool.

5.3.5.3 Sub-theme 3: Challenging perceptions of pain and dementia

Lastly, in the third and final sub-theme, the participants often talked about how pain behaviours can sometimes be overlooked due to a stigma associated with dementia. For example, rather than investigating an atypical behaviour in more depth and ensuring that the residents are pain-free, unusual behaviour can often be disregarded and associated with symptoms of dementia instead.

> *"if somebody was just groaning and it's automatically been described by the care team or a member of staff as oh that's a normal noise that they make it's their dementia it's not looked at as pain"*

> *"we look past the dementia but we look at the person but we don't look at the person from a clinical person point of view we look at the from holistic so we look at how we can meet their needs but not necessarily how we're helping them to manage their [pain] needs"*

This sub-theme could be linked to the capability element of the COM-B mode, it terms of perceived knowledge and awareness of how pain behaviour could be misinterpreted for a “normal dementia behaviour”.

5.4 Discussion

The analysis has identified the most commonly perceived strengths and limitations of using the Abbey Pain Scale and the PainChek® from the experienced perspective of care home staff such as nurses, as well as some perceived critical elements of pain assessment for people with dementia. The most commonly highlighted limitations for the Abbey Pain Scale were the restrictiveness of the tool and the length of time it takes to administer it. The restriction mostly referred to having a small range of pain domains and the scoring system. In comparison, the identified limitations for PainChek® were concerns regarding using an electronic device, such as phone device, in the care homes and the negative impressions which might be reflected by the residents and visiting relatives, and masking the pain by altering the painful behaviour as a result of thinking that the person using the PainChek® is taking a photograph rather than assessing pain in residents.

One of the strengths for the Abbey Pain Scale and the PainChek® was the inclusion of facial expression as one of the main pain domains, which needs to be considered during a pain assessment. Many participants stated that pain is the first point of recognition of pain and identified based on change in facial expressions in residents. The second identified strength of the PainChek® was the ease of use in terms of the small amount of time it takes to complete an assessment, especially when compared to the Abbey Pain Scale.

Finally, the last identified overarching theme focused on factors which were identified as critical during pain assessment of people with dementia in a care home. This included acknowledgement of pain being partially a subjective experience, and therefore highlighted the difficulty of accurate pain assessment through observation.

However, PainChek® mitigates some subjectivity out of observational pain assessment by introducing a fully automated facial expression feature, Next, participants have iterated the importance of familiarity, and how being familiar with a resident prior to an assessment can enhance the observational pain assessment and its accuracy, and lastly some participants challenged a common perception that a change in behaviour in residents is simply down to their dementia, and instead more measures should be taken to investigate whether the change of behaviour is not a consequence of presence of pain.

In terms of feasibility, this study investigated perceived feasibility using a definition by Lichtner et al. (2014), which focuses on exploring convenience and ease of use of particular tools. Convenience and ease of use were investigating by asking questions about limitations and strengths of each tool. Additionally, this study adopted a similar approach to investigating feasibility as a study conducted by Zwakhalen et al. (2012), where feasibility was investigated through conducting structured interviews. The present study used a semi-structured interview approach instead, to allow the participants and the researcher to investigate any elements of the questions asked during the interviews in more depth.

The Pain in Older Adults Knowledge Survey (POAKS) scores were somewhat higher than those reported by Fetherstonhaugh et al. (2016). This could be because the care home staff within the care home where POAKS questionnaire scores were collected consists of a mixture of long-term care home staff, and third-year nursing students on placement. The high mean of scores collected in the present study suggests that the care home staff have a very good knowledge and understanding of pain in people with dementia, some of which can be contributed to experience and skill of working with people with dementia. In addition, the transcripts from the firth main theme could be directly reflected by the high overall mean from the POAKS survey. Good knowledge of pain in older people, as demonstrated by the POAKS results, likely shaped some of the answers provided in the interviews. For example, the participants understood that unusual behaviour expressed by the residents might incorrectly be attributed to symptoms of dementia, rather than pain. Thus, having a good level of prior knowledge and experience of working with people with dementia could help with a more accurate recognition and assessment of pain.

Martin et al. (2005) previously reported some challenges and concerns about pain assessment through focus groups. While these concerns were mostly expressed regarding self-report pain assessment and the potential difficulty for seniors to report their pain easily, Martin et al. (2005) findings can be partially applicable to the present study. For example, if health care professionals, such as those recruited by Martin et al (2005), are expressing concerns about the difficulty to self-report pain in verbal adults, then the concern for non-verbal elders should be increased. The reported concern in relation to pain assessment indicates the lack of knowledge and understanding of pain assessment in verbal and non-verbal individuals who might not be able to understand the pain, which in turn might explain some of the concerning results about ongoing under-recognition and under-treatment of pain (Nègre-Pagès et al., 2008).

It was interesting to see that similarly to the findings by Liu (2013), the participants in the present study also identified the importance of familiarity of residents prior to any observational pain assessment, thus supporting Liu's (2013) findings. This can also be linked to the comments participants in the present study made about the importance of facial recognition as one of the pain domains in both, the Abbey Pain Scale and the PainChek®. If care home staff are able to recognise an atypical facial expression in residents as a result of a good level of familiarity with the resident's typical facial expression, this initial suspicion of presence of pain might subsequently lead to a faster assessment of pain and therefore faster pain treatment and management.

The main limitation of the present study was that the participants have not used PainChek® as a semi-automated observational pain assessment tool before, and therefore they were unable to relate their experiences to it. It was expected that the novelty of the automated facial expression feature will excite the participants, therefore measures in terms of counterbalancing the order of the discussed tools in the interviews were avoided. In order words, participants were always asked about their views and opinions of the Abbey Pain Scale first and the PainChek® second. Some initial limitations of the PainChek® were identified, which will be considered for the future. One of the limitations focused on the uncertainty of implementing the use of smartphone devices within a care home setting. In addition, the author acknowledges

that this study focused on feasibility only, which is only one very small aspect of observational pain assessment. The interview questions were quite open, which allowed the participants to discuss any aspect of feasibility they wished to which may also be seen as a limitation. Instead, the feasibility questions could have included specific and focused sub-questions which may have enabled the researcher and the participant to explore aspects such as user interface, time taken to administer the tool and other elements in much more detail.

Hospital and care home settings have started to implement interventions, which are electronic, to replace any current paper-based policies. This topic, however, is somewhat controversial. Some clinical settings offer and encourage their staff to use clinical application on their smartphone devices, to help them during work, with the intention that the notes which are taken on a smartphone device are uploaded to a shared space where any staff member can access them at any time. This can, therefore, speed up communication between units, departments or specialist clinics and ultimately better access to notes and communication between settings. However, some research suggests that staff members use smartphone devices in an inappropriate way, or may not be able to appropriately assess when a smartphone device needs to be used at work (McBride, LeVasseur, & Li, 2015).

However, the use of smartphones within clinical settings can also have a very positive implication. Smartphone devices used during a regular routine have the capability of changing how healthcare is delivered. For example, using smartphone devices can help merge and integrate multiple technological aspects into a single device which is easily accessible at all times (Putzer & Park, 2010). Thus, providing training and explaining the positives of use of a smartphone device within a care home can help to reduce the concerns which have been identified by participants in this study.

Lastly, the COM-B behaviour change model can be partially applied to the findings of the study. The COM-B approach (developed by Michie, van Stralen, & West, 2011), focuses on ways to improve implementation and design of evidence-based practice through behaviour change interventions. Some of the quotes provided in the analysis section mentioned administering pain killers “just for the sake of it”. In addition, throughout the analysis section, the COM-B model and especially the capability and

opportunity elements were linked to some of the sub-themes and could help to understand how the frequency of the use of observational pain assessment tools could be enhanced in the future. Moreover, while this was not a major overarching theme in the interviews, several comments about administering pain killers as a precaution rather than as a treatment were made.

The COM-B approach can be partially applied here, in a similar manner to the study by Barker, Atkins, & de Lusignan (2016). Barker et al. (2016) applied the COM-B approach to promote the use of hearing aid. When applied to this study, the COM-B approach could be used to promote the use of observational pain assessment tools on a regular basis, rather than sporadically. Doing so could enhance the frequency of assessment using observational pain assessment tools and therefore prevent suboptimal and underutilised tools, which could in turn increase accuracy of pain assessment. That being said, it's also important to note that observational pain assessment in people with dementia tis complex, and while increasing the frequency of use of the observational pain assessment tools alone may contribute to better accuracy of pain assessment, treatment and management, there are other factors, such as workload in care homes, which needs to be considered.

5.5 Conclusion

In conclusion, the following five overarching themes have been identified; perceived limitations of the Abbey Pain Scale, perceived strengths of the Abbey Pain Scale, perceived limitations of the PainChek®, perceived strengths of the PainChek® and critical factors of pain assessment. These themes helped to highlight the strengths and limitations of the Abbey Pain Scale and the PainChek®. The findings of this study can be implemented in the future development of observational pain assessment tools, to help increase perceived feasibility. Additionally, the findings of this study also highlight the positive views and opinions about PainChek® which bear importance for future direction of study as well as future developments and possible release of the app in UK.

6 Chapter Six – Validation of PainChek®

6.1 Introduction

Pain in frail older adults with dementia is a major concern with literature consistently reporting poor treatment and management in terms of inappropriate administration of analgesics and incorrect recognition of presence and severity of pain (Reynolds et al., 2008; Won et al., 2004). Given the evidence that the proportion of individuals with dementia who experience pain is approximately 50% (van Kooten et al., 2016), yet it is still poorly recognised and treated, reiterates the need and importance to develop an accurate, reliable and valid means to recognise and evaluate pain in this frail population (Herr, Bjoro, & Decker, 2006). Generally, in UK care homes, the registered nurses or nursing associates usually administer the observational pain assessment tools, such as the Abbey Pain Scale, to detect presence and severity of pain.

The lack of ability to accurately self-report valid pain in individuals with dementia has already led researchers to develop tools which help recognise the pain, which has previously been outlined in this thesis. In an earlier chapter, the Literature Review (Chapter 2) has identified a gap in pain assessment in people with dementia. This gap identified that despite the fact that many observational pain assessment tools are freely available to assessors, the pain in many people with dementia is still under-detected and undertreated. Additionally, this was further investigated and supported in the Systematic Review (Chapter 3), where the findings confirmed the need for an observational pain assessment tool which is highly valid, reliable and more accurate at identifying and assessing pain in the older people population living with dementia.

Sengupta, Bercovitz, & Harris-Kojetin, (2010) identified several factors which could influence appropriate pain assessment and treatment, including racial and ethnic disparities. Additionally, while there are some underpinning physiological mechanisms involved, pain is largely a subjective experience. Because of this, observer judgement is another factor which could hinder assessment of pain based on the observer's previous knowledge, experience and bias of pain (Goubert, Craig, & Vervoort, 2005).

Further factors such as likeability of the person being observed (De Ruddere et al., 2011) and information about the patient's motivations (Kappesser, Williams, & Prkachin, 2006) were significant factors which hindered accurate and appropriate pain assessment. For example, in the research conducted by De Ruddere et al. (2011), the findings suggested that the patients which were disliked were more likely to have their pain taken less seriously compared to patients which were liked.

The outlined research, the Literature Review (Chapter 2) and the Systematic Review (Chapter 3) has shown that available observational pain assessment tools are subjective, have limited evidence of accuracy, lack consistency, may be subject to bias and are underutilised in practice. Additionally, Stacey (2005) conducted qualitative research with care home workers to explore the constraints and rewards of working in a care home environment and found that care home staff often express the feeling of being overworked which compromises their ability to perform well at a workplace.

The above-outlined concerns suggest the need to further investigate ways, in which we can assess pain more accurately and consequently treat the pain more appropriately. One of the ways to do this is to limit human error or observer bias such racial judgement where white patients are more likely to be prescribed more pain treatment than other ethnicities (Kaseweter et al., 2012), likeability of the patient (De Ruddere et al., 2011) and others. Therefore, PainChek® as a tool which uses a built-in automated feature limits some of the factors which could hinder objective pain assessment (Atee et al., 2017a). PainChek® minimises human error and bias by introducing an automated facial expression recognition technology, which human error and bias by introducing an automated facial expression recognition technology, which utilises real-time facial analysis to detect micro-expressions which are indicative of pain. The automated facial expression technology is combined with other pain domain cues such as the voice, behavioural changes, the movement, changes in activity and the body, to provide an all rounded pain assessment, which utilises all six pain domains recommended to be used by the AGS (2002). PainChek® has previously been validated (Atee et al., 2017a, 2017b) and evaluated (Atee, Hoti, & Hughes, 2018) in Australia, and has demonstrated excellent validity and reliability.

PainChek® is already showing great potential in regards to clinimetric (Hoti et al., 2018) and psychometric (Atee, Hoti, & Hughes, 2018) properties, specifically excellent concurrent validity, intraclass correlation coefficient reliability measure and good discriminant validity and predictive validity. However, this tool is relatively new in comparison to other well-established pain assessment tools (e.g. the Abbey pain scale) and needs to be further validated to ensure its validity and reliability is replicated across multiple cultures and a variety of dynamics and settings. Taking into consideration the previous concerns, the need for a highly valid observational pain assessment tool and the so far excellent results from PainChek®, the rationale for this research is to further investigate the validity and reliability of psychometric properties of PainChek® in a UK setting. It is important to evaluate this newly developed tool across several settings, patient populations and in a variety of cultures, to ensure that the automated facial expression element of this tool can be applied to a wide range of population living with dementia.

Further to this, in the UK, the British Pain Society outlines the guidelines for observational pain assessment in older people with dementia. However, although it has a practical suggestion for a scale, which is Abbey Pain Scale (APS), it does not currently have a single recommendation for an observational pain assessment tool (Closs et al., 2007). Closs et al. (2007) concluded that the most appropriate tool to validate a new observational pain assessment tool against (in this case the PainChek®) would be the APS (developed by Abbey et al., 2004). It is important to note that while both tools utilise all six domains to assess pain, the pain scores and range for pain severity categories differ (table 6.1), therefore several validity and reliability measures will be tested to evaluate PainChek®.

Table 6.1. Comparison of pain category scores between Abbey Pain Scale and PainChek®

	No pain	Mild pain	Moderate pain	Severe pain
APS	0-2	3-7	8-13	14+
PainChek®	0-6	7-11	12-15	16-42

The aim of the quantitative study was to further validate and evaluate the psychometric properties of the PainChek® in UK care homes, using a new operating system (Apple iOS), with a British cohort of individuals living with dementia in a UK care home.

The objectives were:

a) To compare the PainChek® directly against another observational pain assessment tool, in this case, the APS
b) To investigate the psychometric properties of the PainChek® by conducting an evaluation study with individuals with dementia living in a UK care home
c) To investigate whether the PainChek® continues to accurately and reliably recognise and assess pain, despite the deterioration of cognition as a result of the progression of dementia

The present study has taken a pragmatic approach to this study. The time of data collection was not limited to the time of day or location of these pain assessments within the care home. The pain assessments observations took place in communal and shared areas of the care home rather than isolated rooms, to replicate the conditions under which pain assessment observations would usually be completed in those particular settings.

The following two hypotheses were tested:

1. There will be a strong positive significant correlation between the Abbey Pain Scale and the PainChek® pain scores (in overall pain scores, rest pain scores and post-movement scores categories).
2. The reliability tests of the PainChek® will demonstrate at least a substantial interrater agreement, moderate intraclass reliability and satisfactory internal consistency when compared against the Abbey Pain Scale.

6.2 Method

6.2.1 Design and setting

The present correlational study recruited residents from one private non-NHS care home specialised in dementia care based in Nottinghamshire, UK, which at the time of recruitment and data collection, had a Care Quality Commission (CQC) rating of “outstanding”. The care home is divided into four sections, each focusing on a different stage of dementia. The researcher has collected data from two sections of the care home, one that specialised care for individuals with moderate to severe dementia, and one for severe dementia and end-of-life care. The research is conducted with permission of the care homes, and with ethical approval from the University of Derby research ethics committee (see appendix 6.1) as well as the NHS research ethics committee (see appendix 6.2). The research is for a third-party private interest who has no influence on regulation or care arrangements.

The recruited care home focuses on emotionally led support. This means that the priority of the care home is to ensure that people who live with dementia are supported by a team of staff who understand that their emotional needs and wellbeing are key. The staff not only cares for the residents, but also spends time laughing, listening, dancing, being creative, singing and enjoying life with the residents during their stay.

6.2.2 Recruitment

6.2.2.1 Recruitment of the nurse

Prior to the commencement of data collection from recruited participants, it was crucial to recruit a nurse who accompanied the researcher and administered the APS throughout the whole data collection period. Several nurses were approached within the care home and had a discussion with the researcher about their skills and

experience of using the APS, as well as overall knowledge and experience of dementia.

Following the discussions with the nurses and with the recommendation of the care home manager, the researcher decided to recruit a nurse who had previously been included in a variety of research studies, had an experience of research processes and procedures, was enthusiastic, and most importantly, had six years of experience and training of working with the APS.

At the time of recruitment, the nurse had been working in the care home for six years and was therefore very familiar with typical and atypical behaviours of all residents. The nurse was in charge of two care home sections; moderate-to-severe dementia section and end-of-life dementia section, which were the two sections participants were recruited from. The nurse was therefore not only familiar with individual residents but also with the schedule and processes of the care home.

Lastly, the nurse was experienced and competent at administering the APS, as this was one of her responsibilities in the care home. The nurse also had an appropriate pain assessment specific training provided by the care home, which further reinstated her appropriateness and competence to administer the APS.

6.2.2.2 Recruitment of the participants

A priori power calculation indicated that to achieve a power of 0.8 and a large effect size of at least 0.5 (Cohen, 1988) 28 participants were needed. Unfortunately, this number was not achieved due to difficulty of recruiting participants who lack capacity and a higher death rate over winter. Twenty-two participants were recruited from a care home using, which has previously agreed to be part of the study. Managers and owners of the care home indicated that all potential participants recruited from the two sections of the care homes (moderate-to-severe dementia and severe dementia to end-of-life care) lacked the capacity to consent for themselves. Therefore, due to participant's lack of capacity and inability to comprehend the procedures of the study,

consent was obtained through their personal consultee, legal guardian or Power of Attorney specifically for health and welfare, which is in line with Mental Capacity Act guidelines (Mental Capacity Act 2005, 2005). The individual who gave consent on behalf of the participant was most often a close relative who came to visit the participant on a regular basis. Ethical approval was given by the NHS REC as well as University of Derby College Research Ethics Committee at College of Health and Social Care. Table 6.2 provides a summary of inclusion and exclusion criteria for all participants.

Table 6.2. Inclusion and exclusion criteria for this study

Inclusion criteria:	Exclusion criteria:
Diagnosis of dementia	Individuals diagnosed with Parkinson's Disease
Documented history of chronic pain condition (e.g. arthritis) OR residents which are often treated for pain due to pain complaints	Individuals who are partially or fully unable to exhibit facial features (such as some stroke survivors or those with facial deformities)
Residents of 65 years of age or older	Individuals with a significant mental health condition which could result in unnecessary distress

	Individuals who have been advised not to take part by their GP, staff or family member

Participants diagnosed with Parkinson's Disease were excluded, as their facial features could have been compromised due to the nature and progress of the condition (Parkinson's Foundation, 2019). Further to this and for the same reason, residents who were partially or fully unable to exhibit facial features or those with facial deformities have also been excluded from this study. Furthermore, stroke survivors who experienced facial palsy were also excluded from this study. Stroke can often result in facial palsy due to the damage of the facial nerve, where mostly the lower part of the face, such as the mouth and cheeks are affected (Facial Palsy UK, 2017).

Additionally, the study also required the recruitment of one or two nurses who were trained and competent in the use of APS. One Registered Nursing Associate who had previous training with APS was recruited. Prior to data collection, the PainChek® rater and the nurse had a few trial runs of pain assessment to ensure familiarity with the study protocol. Further to this, the researcher completed training for the use of PainChek® to ensure familiarity and competence. The training consisted of completing an online training module which has been provided by the PainChek® team and Dementia Training Australia (DTA). The training which the researcher completed prior to data collection, was the same as the training provided to others who administer PainChek® in Australia.

6.2.3 Materials

An electronic device – Apple iPhone 6s using iOS version 12.2 was used to download and use PainChek® app during data collection (see appendix 6.3). It is important to note that this was not a personal phone, but a secure, password-protected professional-use only device which did not contain any personal documents, apps or any other personalised widgets.

Additionally, three scales were used altogether. First, before the collection of any data, the researcher completed the Mini-Mental State Examination (MMSE) (Folstein, Folstein, & Mchugh, 1975) for each participant, to gauge the severity of cognitive impairment. Once this score was obtained, the nurse and the PainChek® assessor then assessed pain in the participant at rest, and again immediately after movement. The assessment measure taken at rest replicated comfort condition, whereas the assessment measure taken immediately post-movement prompted nociceptive pain. Pain was assessed using the APS and PainChek®.

6.2.3.1 Mini-Mental State Examination (MMSE)

The MMSE was first developed by Folstein, Folstein, & Mchugh (1975) and it is a widely used scale to test level of cognitive impairment among the older people. Each participant was assessed for the severity of cognitive impairment at the start of the study, and then again at the end. This assessment took approximately 10-15 minutes to complete. The scale is divided into 5 sections, each focusing on different aspect of cognition:

Orientation: This aspect of the MMSE asks questions regarding the current location and date at the time when questions are asked. For example, the assessor would ask questions such as “Can you tell me the name of this town?”

Registration: The second aspect of this scale focuses on the individual’s object registration. In this task, the assessor names three unrelated objects (the authors of MMSE recommended the use of apple, penny and table) and asks the patient to repeat them. After the patient has repeated all three objects successfully, the assessor tells the patient to try remembering the three objects as the assessor will ask the patient to recall them again in a little while.

Attention and calculation: The third aspect of this scale requires the patient to do some counting or spelling. For example, the patient is asked to begin at 100

count backwards by sevens. If the patient cannot perform this task, an alternative task is to ask the patient to spell the word “world” backwards.

Recall: The next aspect is recall. In this section, the assessor asks the patient to recall the three unrelated objects from the registration task.

Language and praxis: Lastly, this stage focuses on naming, repetition, three-stage commands, reading, writing and copying. Firstly, the patient is asked to name two objects which the assessor point to (these are a wristwatch and a pen/pencil). Secondly, the assessor asks the patient to repeat the following phrase “no ifs, ands, or buts”. Next, the patient is given a blank piece of paper and is asked to take the paper with their right hand, fold it in half and place it on the floor. The next element is reading. The patient is given a piece of paper, which has “close your eyes”, printed on it. The patient is then asked to read and follow this instruction. Next is the writing task. The patient is asked to write a sentence on the paper. This sentence must contain a subject and a verb, and it must make sense. Last, the patient is presented with a simple picture of two intersecting pentagons. The patient is asked to copy the two shapes exactly as it is.

If all of the tasks above are performed correctly, they add up to 30 points. A score of 20-24 indicated mild cognitive impairment, moderate cognitive impairment is indicated with a score of 13-20 points and severe cognitive impairment is indicated with a score of 12 or less (Alzheimer’s Association, 2019).

6.2.3.2 Abbey Pain Scale (APS)

The APS (Abbey et al., 2004) is a movement-based assessment and one of many observational pain assessment tools used by assessors to identify pain. Movement-based assessments require the assessor to observe the individual in pain at rest as well as during movement (e.g. during a transfer, showering, pressure area care). This tool has been designed specifically for individuals unable to communicate, such as individuals with end-stage dementia who are potentially in pain. It utilises all six domains recommended by the American Geriatrics Society (AGS, 2002), with the pain

scores ranging from 0-18, where higher the score is associated with higher indication of pain presence and severity.

After the initial observation and pain assessment, the instructions for the APS require the assessor to complete a second evaluation for the same patient following the initial observation. If the pain score has stayed the same or has worsened, the tool urges the assessor to consider further intervention and act as appropriate. Additionally, the assessor should continue to monitor and evaluate the patient hourly until the pain score decreases to mild pain. Then, the patient should be evaluated every 4 hours for the next 24 hours while the patient is being treated for pain.

The APS has four pain categories. A score of 0-2 indicates no pain; a score of 3-7 indicates mild pain, 8-13 moderate and 14+ severe pain. There are six domains assessed (see Table 6.3), which each require a score of 0-3 before the total score is added up. The assessor scores each domain appropriately, where 0 indicates absence of the behaviour, 1 is mild, 2 moderate and 3 severe presence of the explained behaviour.

Table 6.3. APS Pain domains with examples of behaviour

Pain domain/question	Example of behaviour
Vocalisation	Whimpering, groaning, crying
Facial expression	Looking tense, frowning, grimacing, looking frightened
Change in body language	Fidgeting, rocking, guarding part of the body, withdrawn
Behavioural change	Increased confusion, refusing to eat, alteration in usual patterns

Physiological change	Temperature, pulse or blood pressure outside normal limits, perspiring, flushing or pallor
Physical change	Skin tears, pressure areas, arthritis, contractures, previous injuries

Additionally, if the pain persists, the assessor is urged to undertake a more comprehensive assessment of all facets of the patient care such as further investigation into the pain history of the patient, and further monitor the patient closely over the next 24 hours, while continuing to carefully administer interventions to reduce pain severity. If there is no improvement of pain severity over the next 24 hours, the assessor is urged to contact the GP or a responsible specialised clinician to take further actions.

6.2.3.3 PainChek®

PainChek® (Atee, Hoti, & Hughes, 2018) is a smartphone application (app) which utilises automatic facial recognition technology to scan the face of an individual to detect micro-facial expressions indicative of the presence of pain. The micro-expression facial pain data are then combined with non-facial pain cues (see Table 6.4) to calculate an overall pain score, which is indicative of pain presence and severity. PainChek® automated facial expression element utilises the Facial Action Coding System (FACS). The FACS is a complex and comprehensive system based on facial anatomy which is used to detect facial movement (Ekman & Friesen, 1978). This system is used to recognise changes (contraction or relaxation) of facial muscles. By looking at a selection of key muscle actions, it is possible to identify the level of pain being shown through a particular facial expression. In this study, the three-second version of automated facial expression feature was used, meaning that the camera only took three seconds to scan the face of the participant.

Table 6.4. PainChek® pain domains with pain descriptions

Pain domain	Pain descriptors
Face	Brow lowering, cheek raising, tightening eyelids, wrinkling nose, raising upper lip, pulling corner lip, mouth stretch, parting lips, closing eyes
Voice	Noisy sounds, requesting help, groaning, moaning, crying, screaming, loud talk, howling, sighing
Movement	Altered random movement, restlessness, freezing, guarding touching, moving away, abnormal movement, pacing wandering
Behaviour	Introvert, verbally offensive, aggressive, fear or extreme dislike of touch, people, inappropriate behaviour, confused, distressed
Activity	Resisting care, prolonged resting, altered sleep, altered routine
Body	Profuse sweating, pale flushed, feverish cold, rapid breathing, painful injuries, painful conditions

As with the APS, PainChek® utilises all six domains recommended by the AGS (2002). The PainChek® utilises a binary scale, which indicates whether each item within each pain domain is either present or not present. This information is then used to

categorise the severity of pain, where a score of 0-6 indicates no pain, a score of 7-11 indicates mild pain, 12-15 for moderate pain and anything above 16-42 indicates severe pain. However, unlike the APS the 42 pain descriptors of PainChek® are scored on a binary “yes” or “no” basis depending on presence of the descriptor (where “yes” = 1 and “no” = 0). The scores from the descriptors which are marked as “yes” add up to an overall pain score. In this study, the Apple iOS version 12.2 of PainChek® was evaluated.

6.2.4 Procedure

The study was approved by the NHS Research Ethics Committee (REC) and the University of Derby College Research Ethics Committee (CREC) through the College of Health and Social Care in September 2019. This study also had approval from the participating care home to invite eligible residents to take part in the study.

Prior to the recruitment process, the researcher spent four months visiting and observing processes and routines relevant to the conduct of the study in the care home. This helped the researcher to familiarise themselves with the care home staff and residents, as well as integrate themselves and become part of the care home. Additionally, the researcher has arranged a short meeting with staff of the care home which helped identify potential participants based on given inclusion and exclusion criteria. The meeting explained the aims of the study and how to identify potential participants within the care home. The staff members had the opportunity to ask any questions or voice their concerns during the meeting. The staff had no concerns about the design or protocol of the study.

Due to the nature of the study, all of the participants lacked the capacity to consent for themselves. Due to this, careful measures were taken to obtain informed consent for each participant. To do this, letters were sent to consultees of all potential participants which were previously identified by the care home managers and staff and met inclusion and exclusion criteria. This procedure is in line with Mental Capacity Act (2005), which states that the researcher needs to identify an appropriate body (i.e.

power of attorney, legal guardian or a consultee) in relation to a person who lacks the capacity to consent (Provision 31, Section 1). The identified body must have no connection with the project (Provision 32, Section 3), and the researcher must give the identified person an informed consent about the project. The identified person will make a decision based on what, in their opinion, the participant's wishes and feelings about taking part in the project would be likely to if they had capacity in relation to the matter. This process complies with current legal consent practices. The consultee (a relative of the participant), who has given consent for the participant, had the right to withdraw the participant from the study if they feel that the participant no longer wishes to continue.

Each consultee was given a recruitment envelope, which included an Invitation to Participate, Participant Information Sheet for Consultee, a leaflet about PainChek® and an Informed Consent form (see appendix 6.4) with an envelope and a first-class stamp to return the consent back to the researcher. Additionally, relatives and consultees were approached and received the recruitment information during the visits to the care home in order to increase the speed of the recruitment process. All consultees (those approached within the care homes and those who had recruitment envelopes sent to their address) had the time to read all documents carefully and ask the researcher any questions either in person or via phone or email.

Once valid informed consent has been given, baseline MMSE scores were collected. The researcher was accompanied by the same nurse at all times. Paired ratings were collected from each participant at rest and immediately post-movement (see Figure 6.1). Paired ratings refer to a total of four pain assessments taken during one session. In other words, two assessments (one from APS one from PainChek®) were obtained during a restful state (e.g. participant sitting or lying down), following by two assessments (one from APS one from PainChek®) obtained immediately after movement (e.g. participant was asked to stand up and sit down, or after a transfer from bed to a wheelchair). The researcher and nurse initiated the movement carefully, and would only ask the participant to move if it was safe to do so. Both, the researcher and the nurse approached the participant and completed the pain assessment simultaneously to mitigate any changes in expressed behaviour.

The simple movement often involved the participant standing up, taking a few steps or if they were less mobile, the participants were asked to move their arms and legs while seated. If the participant was fully immobile, the researcher would take a rest assessment prior to a transfer (e.g. from bed to a chair), and a post-movement assessment after the transfer. The paired assessments were collected from participants over a period of 16 weeks, until data saturation was reached (saturation was considered when additional data collection would not have changed the findings of the study). Once all paired pain assessments were completed, the researcher completed a final MMSE assessment for each participant, which was accompanied by a nurse at all times to ensure participant and researcher safety. Once the final MMSE scores were obtained from all participants, participants were thanked individually and a debrief was sent out to consultees of participants.

Lastly, it is important to note that the researcher only collected data from the care home once or twice a week. Unless there is a directive from a GP, it is unusual for care homes to obtain observational pain assessments more frequently than this, especially when residents are perceived as not experiencing pain. Therefore, to prevent disruption of daily living and activities in participants, the researcher only visited to collect data once or twice a week. Furthermore, the frequency of pain assessment is somewhat unusual if done multiple times per week unless there is a directive from the GP to do so. The standard care home procedure or practice is to assess pain once a week unless the resident sustained a painful injury or starts showing behaviours which are unusual and concerning.

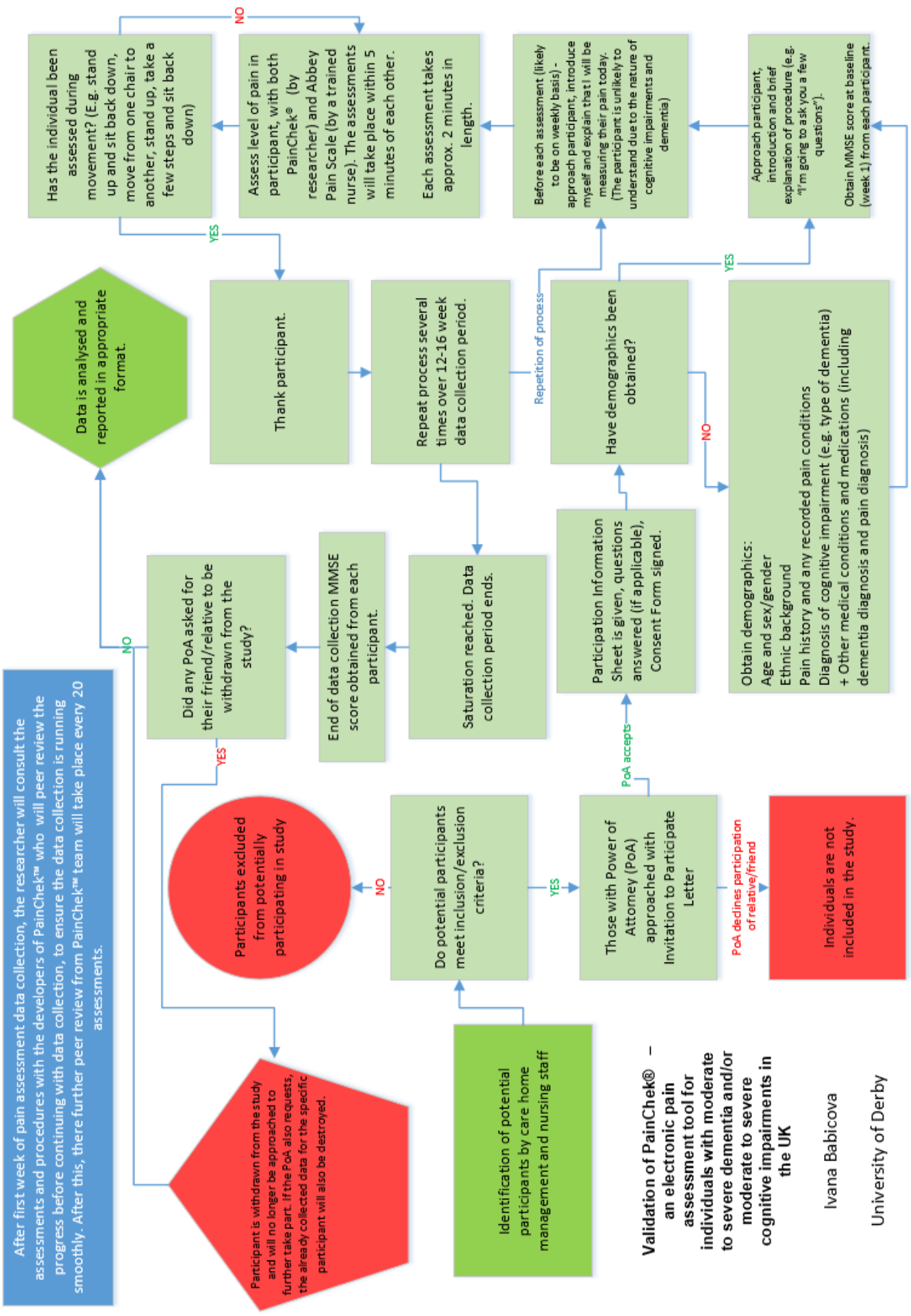

Figure 6.1 Study protocol flowchart

6.2.5 Data processing and checking

APS scores were manually transposed from original paper copies into an Excel spreadsheet. Individual scores from each pain domain as well as total pain scores were recorded in a spreadsheet. In a similar way, the individual and total scores from the PainChek® app were manually transposed to Excel spreadsheet, in preparation for data investigation and analysis. Upon the completion of this process, the data were first reviewed to ensure consistency in the data set. Transposition errors were noticed in the raw data set, specifically in the body and the activity domains of PainChek®. This led to further investigation which resulted in additional checking for transposition errors and re-entering data which were thought to be incorrect. The raw data, which were date and time-stamped, were compared against internal care home notes. The internal care home notes are written by nurses on shift and stored electronically. The researcher was specifically looking for notes which indicated any changes in sleeping pattern, general routine or behaviour, whether the participant was particularly introverted, verbally offensive, aggressive or was refusing care on the day of the visit. The process to ensure that the data set is correct and error-free required the researcher to undertake the following two steps:

1. It has been noticed that in cases of some participants, the last two items of the body domain; painful injuries and painful conditions, were not always consistent. When the data set was ordered by date and time of data collection, at times, the item for the presence of pain condition would change from week to week. For example, a data set collected from a participant on a Monday would indicate that this participant has the presence of a painful condition (such as arthritis or osteoporosis) but the data set collected from the same participant on Thursday would indicate that the painful condition is no longer present. Additionally, the presence of a painful condition for the same participant would reappear again few days later. This is an example of an error in the data set, as it is extremely unlikely that the painful chronic condition would simply disappear and reappear again. Once a participant has been diagnosed with a painful chronic condition, the data set should have consistently demonstrated this throughout the 16-week data collection period, unless otherwise specified.

To correct this error, the researcher has investigated the demographic data collected at the start of the data collection period and corrected any potential inconsistencies by looking through the internal care home notes and checking for dates of chronic

pain condition diagnoses, and any changes in severity or development of additional painful conditions. If a diagnosis of a painful condition was present at the start of the data collection, the painful chronic condition would have been present throughout the data collection, unless otherwise specified. To further enhance the trustworthiness of these corrections, the care home notes for each participant were checked for the type and severity of a chronic painful condition of each participant. Additionally, if there was lack of clarity whether a painful condition was present from the start or whether an additional painful condition has been developed over the 16-week data collection period, the researcher crosschecked this with the nurses and the nursing records, which had the information logged and dated, allowing the researchers to correct data. Based on this information, the item of presence of painful condition was corrected manually in Excel spreadsheet, before continuing to statistical data analysis.

2. In a similar way to the error outlined above, the second error which was noticed in the raw data set was the lack of presence of any items in the activity domain in PainChek®. The items in the activity domain look at changes in sleeping pattern (prolonged resting or altered sleep), altered routine in general or participants resisting care. To correctly answer whether these behaviours were present in participants, the researcher was required to ask the staff on shift about this information. In majority of the cases, the staff on shift either (a) were unsure because they have not worked the night shift or were not present during handover (b) the nurses would not be aware of any behaviour changes which would apply to this pain domain, or (c) the nurses would indicate that the behaviour in this domain were perhaps present, but not a cause for concern or nothing out of the ordinary. As a result of this, the scores in the activity domain of PainChek® were in most cases marked as not present.

   Upon closer investigation of the raw data and specifically the activity domain, it has become clear that the scores do not truly represent the potential behaviour

changes expressed and experienced by the participants, and therefore are untrustworthy. Therefore, it was decided that notes, and internal care home records will be investigated for any changes in sleeping patterns, behaviour patterns or resisting of care notes retrospectively to correct any values for behaviours which were deemed as not present as a result of lack of knowledge from the care home staff at the moment. All data collected had a date and time stamp present, therefore the researcher was able to track back and identify information regarding this behaviour.

The researcher has spent several hours searching and investigating through internal care home records about participants. This was done in order to ensure consistency and no missing entries in the data collected for all PainChek® domains. The internal care home records and the collected data sets had a date and a time stamp present, which allowed to match missing data from the activity domain to internal care home records. The researcher would only look at records, which were uploaded to the internal system on the morning of a data collection visit. The staff on shift are trained to report any unusual behaviour observed during the night, every night and in the early hours of the morning.

In this case, the only time the staff would not report an unusual behaviour, is if the resident has slept throughout the night without any problems. In majority of the cases, the staff reported anything from wandering, waking up during the night, crying, screaming, asking for help, demanding food or drink. The reports also included notes about morning routine personal care, which usually happened during morning hours (between 5 and 10 am). The personal care reports included notes about whether the resident accepted or rejected medication, personal care (e.g. change of clothes, morning shower or oral hygiene), whether they were introverted, calm, happy, verbally offensive or aggressive or whether they refused to get up and demanded further resting period.

It is important to note that this is *not* a criticism of the care home staff. At times, it was not possible to access the internal records or systems as this would have been very time-consuming. Additionally, only specific care home staff (registered nurses and nursing associates) which were present during handover and have

responsibilities such as pain monitoring and management need to be aware of information such as changes in sleeping pattern and altered routines.

To ensure a high level of integrity and trustworthiness of the data set, the researcher's supervisor double-checked data transposition from both PainChek® and Abbey Pain Scale. A randomizer tool was used to randomly select 20% of the raw data (61 APS and PainChek® data sets out of 302), to be cross-checked by a member of the supervisory team. The data were cross-checked, and no issues were found.

6.2.6 Data analysis

Next, prior to analysis of data, several measures and assumptions need to be considered to ensure even distribution of results. First of all, there are four assumptions of normality which the raw data should meet to pass criteria for a Pearson's correlation test; the data should be continuous, have a linear relationship, be outlier free and the variables need to be approximately evenly distributed. The first assumption states that the data needs to be continuous, i.e. the measured variables must be measured at an interval or ratio level. The data in this study was measured on an interval level, as it uses two numeric scales (PainChek® and APS) and therefore meets this assumption of normality. To meet the second assumption of a parametric test, a linear relationship between two variables needs to be considered. This is often measured using a scatterplot, where the two variables are plotted against each other. In this case, the two variables (overall APS scores and overall PainChek® scores) were investigated.

The next assumption which needs to be considered looks at significant outliers in the raw data set. The presence of significant outliers can also be investigated using scatterplots. The scatterplot for overall pain scores between APS and PainChek® has shown no presence of outliers, and therefore this assumption of normality was also met. Additionally, to further investigate outliers, overall z scores for skewness and kurtosis were calculated manually. Skewness is a measure of the asymmetry of data, whereas kurtosis measures how 'peaked' the distribution of raw data is. The calculations have shown that the PainChek® overall pain scores were within the +/-

1.96 range which is sufficient to establish normality of the data (Ghasemi & Zahediasl, 2012). However, this was not the case for overall scores of the APS. The researcher considered removing or Windsorizing individual data which demonstrated higher individual z scores, however as argued in Chapter 7, it is important to include and investigate data from all participants. Doing so allows the results of the data set to be more organic, pragmatic, practical and accommodative of real-life scenarios in clinical practice. To further support this decision, the aim of this study was not to demonstrate the even distribution of scores but to demonstrate that the two tools consistently agree on the presence and severity of pain in individuals. When individual histograms were compared between APS and PainChek® patient assessment scores, the overall pain assessments scores for APS was slightly positively skewed.

The final assumption of normality focuses on even or approximately even distribution of the data set. This can be investigated by running a Shapiro-Wilk test. The Shapiro-Wilk test needs to demonstrate a *p* value of >.05, to suggests that the data are significantly not normally distributed. The data did not demonstrate evenly distributed scores, therefore suggesting a skew within the data set. This means that the data violated one of the four parametric assumptions for even distribution and data normality. Even distribution was not expected, as the ethical implications of this study and pain procedures of the care home would perhaps have been questioned if a larger proportion of participants were experiencing severe pain at the time of the study. These findings were expected and are in line with what would be observed during regular care. Finally, the frequency of scores in the histograms was investigated. Both tools have demonstrated the highest frequency of the score which was the lower threshold of mild pain category. In other words, the most frequently scored pain value for APS was three, and seven for the PainChek®. This, therefore, demonstrates the consistency of pain presence for both tools.

The data have met three out of four assumptions of normality. Ghasemi & Zahediasl (2012) review statistical literature in their article, and state that violation of normality in larger sample sizes (>30 or 40) should not cause major problems, therefore implying that parametric tests such as Pearson's correlation coefficient can still be used even when the data are not normally distributed. While this study only recruited 22 participants, 302 paired within-subject data sets were collected therefore

demonstrating a large sample size. Conversely, de Winter, Gosling, & Potter (2016) recommends the use of Spearman's analysis for data where outliers are present. Due to some debates surrounding the importance of parametric assumptions and even distribution in correlational analysis, this study has adopted both approaches and reports the results using a parametric Pearson's correlation, as well as Spearman's correlations.

6.3 Results

6.3.1 Demographic characteristics of the participants

Overall, 302 paired assessments were collected from 22 participants. Out of the 302 paired assessments 179 were conducted during rest and 123 were at immediately post-movement.

Twenty-two care home residents were recruited using an opportunity sample. From the total sample of recruited participants, not all were assessed by APS and PainChek® on every visit. Only participants who were available on the dates and times the researcher visited the nursing home were assessed. For example, sometimes participants were not present at the care home at all due to GP or family visits, and other times participants were sleeping. The participants had a variety of dementia diagnoses, pain conditions and demographic background information (see Table 6.5). Two residents were excluded from the analysis as they were deceased. Given the demographic prevalence of dementia, it is unsurprising that the majority of the participants were female (77%).

Table 6.5. Clinical and demographic characteristics of participants

Characteristics	
Mean age (SD), years	84.7 (5.6)
Median age (range), years	85.5 (74-95)

Gender, N (%)	
Male	5 (23)
Female	17 (77)
Ethnicity, N (%)	
White British	21 (95.5)
Black British	1 (4.5)
Baseline mean dementia (MMSE), score (SD)	5.8 (5.3)
Median MMSE (range)	4.5 (0-17)
End of study mean dementia (MMSE), score (SD)	3.6 (4.5)
Median MMSE (range)	2 (0-14)
Mean length of residency (SD), months	25.8 (25.5)
Median lengths of residency (range)	14.5 (3-83)
Diagnosis of dementia, N (%)	
Alzheimer's Disease	10 (45.5)
Mixed Dementia	6 (27.3)
Vascular Dementia	3 (13.6)
Other/Unspecified Dementia	2 (9.1)
Korsakoff Dementia	1 (4.5)
Diagnosis of pain conditions, N (%)	
Arthritis	5 (22.7)
Osteoporosis	6 (27.3)
Osteoarthritis	2 (9.1)
Other musculoskeletal pain	11 (50.0)

Each participant was assessed for deterioration of cognition over the 16-week study. The first MMSE assessment was obtained at baseline (week 1), and final MMSE assessment was obtained at the end of data collection (week 16). The first MMSE assessment was obtained at baseline (Week 1), and final MMSE assessment was obtained at the end of data collection (Week 16). At the time of enrolment three residents were classified as having moderate dementia and 19 severe dementia based on their MMSE scores. During the course of the study, two residents died, both of whom had severe dementia (MMSE scores of 2 and 4, respectively). Pain assessment

related data for all residents can be found in Table 6.6. In addition, from Table 6.7, it can also be seen that participant generally scored higher across pain categories in the post-movement condition compared to rest condition and moderate pain was only detected immediately post-movement. Lastly, the difference between the rest pain scores and post-movement pain scores obtained from PainChek® was statistically significant (t = -4.610, df = 122, p < .001), suggesting that the pain scores collected for post-movement were significantly higher, than those collected at rest.

Table 6.6 Pain assessment related data of residents (n=22) who underwent pain assessment using the PainChek®

	Number (%)	Mean (SD) per participant
Pain assessments	302 (100)	15.20 (10.08)
Rest	179 (59.27)	9.05 (4.50)
Post-Movement	124 (40.73)	6.15 (5.41)
Pain Scores (median: 5, range: 0-15)		5.29 (2.58)
Pain categories		
No pain	203 (67.22)	
Mild pain	94 (31.13)	
Moderate pain	5 (1.66)	
Severe pain	0 (0)	

Alzheimer's Society (2018) states that the rate of progression of cognitive deterioration varies, where Alzheimer's disease seems to have the slowest progression compared to other types of dementias. However, there is not a standard rate of deterioration which can act as a guideline, as the rate of progression also depends on other factors

such as genetics, secondary diagnoses such as heart condition or diabetes, or the time of onset of dementia (Alzheimer's Society, 2018).

Table 6.7 Mean and Standard Deviation (SD) scores across pain categories collected from PainChek®

Pain categories, Mean (SD)	Rest scores	Post-movement scores
No pain	3.88 (1.54)	3.86 (1.32)
Mild pain	7.89 (1.06)	8.45 (1.30)
Moderate pain	-	13.57 (0.79)
Severe pain	-	-

The following three pain assessment categories were explored:

1) The overall correlation between APS and PC pain scores
2) Correlation between APS and PC pain scores at rest
3) Correlation between APS and PC pain scores post-movement

6.3.2 Correlation between the Abbey Pain Scale and PainChek® for overall pain scores

The overall scores (pain assessments taken during rest and immediately post-movement) were analysed. The overall mean for PC pain scores were higher (M = 6.729, SD = 2.659) than overall mean for APS pain scores (M = 3.566, SD = 1.421). This was expected as the scoring scale for APS range from 0–18, whereas the scoring scale for PainChek® ranges from 0-42. Distribution and normality of data was screened using Shapiro-Wilks test, as well as examining histograms, normality curves, scatterplots, individual z scores and skewness and kurtosis values.

Pearson's *r* and Spearman's *rho* revealed a high positive significant correlation between overall PainChek® pain scores and overall APS pain scores (r_p =.818, r_s =

.823, N = 302, p<.001, one-tailed). Furthermore, the overall pain scores between APS and PainChek® have demonstrated satisfactory internal consistency (α = .810) (Bland & Altman, 1997), moderate single measure intraclass correlation (ICC = .680) (Koo & Li, 2016) and substantial inter-rater agreement (κ = .719).

6.3.3 Correlation between the Abbey Pain Scale and PainChek® pain scores post-movement

The second aim was to investigate the validity and reliability of pain scores immediately post-movement. In line with the direction of previous findings, the mean was higher for PainChek® post-movement scores (M = 7.912, SD = 2.576) compared to APS (M = 4.122, SD = 1.597), significant Shapiro-Wilks test of normality.

Concurrent validity was tested using Pearson's and Spearman's correlations coefficient, which demonstrated a high significant positive relationship for post-movement scores between PainChek® and APS (r_p =.810, r_s = .751, N = 123, p<.001, one-tailed). Internal consistency was satisfactory (α = .841), intraclass correlation for single measures was moderate (ICC = .725) and an almost perfect interrater agreement was (κ = .841).

6.3.4 Correlation between the Abbey Pain Scale and PainChek® pain scores at rest

The means for rest assessment pain scores were higher for PainChek® (M = 5.910, SD = 2.399) than APS (M = 3.184, SD = 1.144). Similarly to overall scores for APS and PainChek®, this condition also demonstrated positively skewed histograms and significant Shapiro-Wilks test. For the same reasons as in the above section, a parametric Pearson's test was conducted.

Pearson's r and Spearman's rho for the rest condition also demonstrated a very strong, positive significant correlation between APS and PainChek® pain assessment scores at rest (r_p =.792 r_s = .830, N=179, p<.001, one-tailed). Furthermore, a

satisfactory agreement (α = .762), moderate single measures intraclass correlation (ICC = .615), and a substantial agreement (κ = .762).

6.4 Discussion

The findings of this validation and psychometric evaluation study of PainChek® demonstrated further evidence that this pain assessment tool would be a suitable instrument for the assessment of individuals living with moderate to severe dementia, therefore supporting the experimental hypothesis. This study provides further evidence that PainChek® had a strong concurrent validity (Hinkle, Wiersma, & Jurs, 2003), substantial to almost perfect interrater agreement (Cohen, 1960), good internal consistency (Bland & Altman, 1997) and moderate intraclass correlation (Koo & Li, 2016), which was in line with findings of the previous validation studies (Atee et al., 2018; Atee, et al., 2017a, 2017b). It is important to note that PainChek® consistently demonstrated these values at rest as well as post-movement.

Furthermore, the study collected MMSE scores at baseline, and again at the end of the study. The comparison of the baseline and end of study scores have, unsurprisingly, demonstrated a deterioration and decrease in MMSE scores across all categories of all participants over the 16 weeks. This is because deterioration of cognition is expected as a result of the progression of dementia, which has been reported in the past (Flicker et al., 1991; Giebel et al., 2014). The aim of this study was to demonstrate that the two tools continued to consistently identify severity and presence of pain over the 16-week data collection period, despite the progression or stage of dementia and its worsening of symptoms associated with the deterioration. There are clinical implications for this finding, suggesting if PainChek® is used on regular basis in UK care homes, it is able to continuously provide an accurate pain reading for all individuals over a period of time, regardless of deterioration of symptoms or functional status, therefore overcoming the potential human error and bias which may occur in health care professionals who have daily contact with the individuals.

Herr et al. (2006) specified a range of correlational values for concurrent validity to be met or exceeded for new observational pain assessment tools. These correlational values outlined need to be at least 0.4-0.6 for a new pain assessment tool to be classed as adequate. In this study, PainChek® has exceeded these correlations (r = .818 for overall pain assessment; r = .792 for pain assessment at rest and r = .810 for pain assessment immediately post-movement), therefore demonstrating its suitability as a new pain assessment tool for people with moderate to severe dementia. Some pain assessment tools have also demonstrated similar concurrent validity values (for example Husebo et al., 2007), however other tools such as PACSLAC have demonstrated much lower correlation coefficients (for example Sheu, Versloot, Nader, Kerr, & Craig, 2011).

During the development and validation of Mobilization-Observation-Behavior-Intensity-Dementia Pain Scale (MOBID), Husebo et al. (2007) have reported high to excellent intraclass correlation coefficient (r = .70 - .96), high interrater consistency (α = .90) but poor as well as excellent interrater agreement (κ = .05 - .84). Most of the results for MOBID seem to demonstrate excellent reliability and validity. The limitation of the development and validation of MOBID is the varying degrees of interrater agreement score, ranging from none or slight agreement to almost perfect agreement. The highest agreement was demonstrated for “pain noises” pain domain, as these items are easy to recognise and assess based on the sounds the residents are making during an assessment. The lowest agreement was identified in the “facial expression” and “defence” pain domains. Specifically, “facial expression” was reported to be the most commonly observed pain behaviour; however, it demonstrated the lowest agreement between the raters. The PainChek® has been trained to detect facial micro-expressions which are indicative of pain. The PainChek®, therefore, eliminates the chance of non-agreement between raters by using a semi-automated electronic facial recognition technology, which does not rely on manual human input of pain presence and severity for the facial expression pain domain. This gives PainChek® an advantage over other observational pain assessment tools which require the assessor to score the facial expression manually, as the face domain is often problematic, difficult to score and remains to be one of the most poorly scored domains (Monroe et al., 2015).

Unlike the results from the present study and the results from the MOBID study by Husebo et al. (2007), the results from Sheu et al. (2011) demonstrated a much weaker correlation coefficient. In their study, 6-second video clips of individuals experiencing mild, moderate and severe pain were recorded. The clips were shown to 5 raters who were asked to assess the facial expression components using Doloplus-2, Mahoney Pain Scale, Abbey Pain Scale, PACSLAC, NOPPAIN and PAINAD. The results have shown that Pearson's correlation coefficient for mild severity demonstrated negligible correlation (mean *r*=.25), moderately positive correlation for moderate pain (mean *r*=.55) and moderately positive correlation for severe pain (mean *r*=.53).

Furthermore, each of the six pain assessment instruments used in this study was compared and analysed for interrater reliability using Cohen's kappa. The reported κ values were very low, with the means ranging from 0.04 (none to slight agreement) to 0.42 (moderate agreement). A higher agreement in κ means was observed as pain severity increased across all six pain assessment tools. These validity and reliability results are much lower than the results found in the present study, demonstrating superiority of PainChek® in terms of strength of correlation and interrater reliability. That being said, it is important to note that the raters who assessed the severity of pain in the video clips were not qualified or trained to do so. They were recruited using opportunity sample on a first come first serve basis, and only needed to meet two inclusion criteria; be over the age of 19 years old and have a healthy vision. While they have been shown how to use each of the six pain assessment tools correctly, they were likely not to have any knowledge or education regarding manifestation of pain in a form of behaviour in a cohort with dementia. Therefore, result from Sheu et al. (2011) might not be truly representative of the validity and reliability of the six pain assessment tools.

However, most of the six pain assessment tools which were utilised in the study by Sheu et al. (2011) also formed part in the development of a newly developed observational tool, which combines fifteen items from six already existing observational pain assessment tools. In this study, a Delphi-like method was used to reach a consensus to develop a 15-item meta-tool called PAIC15 (Kunz et al., 2019). The PAIC15 scale as well as e-training is freely available online and is currently available in English, German, Danish, Dutch, Italian, Spanish and Chinese. However,

while the PAIC15 was developed by combining previously reported strengths and excluding previously reported weaknesses of pain items and domains from clinical and experimental studies, the tool does not utilise a binary scale. Instead, the tool prompts the assessor to score pain on a 0-3 scale, where 0 suggests that a pain item is not present, 1 suggests that pain item is present to a slight degree, 2 to a moderate degree and 3 to a great degree. An additional option for "not scorable" has also been incorporated. However, the non-binary scoring system could fail to mitigate subjectivity and therefore accuracy of the results. Subjectivity in terms of scoring on a Likert-based scale has previously been discussed in Chapter 5.

6.4.1 Comparison of findings between Atee et al. (2018) and present study

The results of the present study further support the findings reported by the first psychometric evaluation of PainChek® study by Atee et al. (2018). Similarly to the present study, Atee et al. (2018) tested reliability and validity of PainChek® against the APS, using 400 pair assessment (rest and immediately post-movement) in Australian residential aged care facilities. The reported results have demonstrated very high positive correlation when measuring concurrent validity between PainChek® and APS (guidelines outlined by Hinkle et al., 2003), excellent intraclass correlation (guidelines as outlined by Koo & Li, 2016), almost perfect inter-rater agreement (as per Cohen, 1960) and satisfactory internal consistency (guidelines outlined by Bland & Altman, 1997). A comparison of results between the two studies are outlined in Table 6.5.

Table 6.8 Comparison of results between Atee et al. (2018) and present study

	Atee et al. (2018)	Present study
Concurrent validity (Pearson's correlation)		
Overall	0.911	0.818
Rest	0.896	0.792
	0.904	0.810

Post-movement		
Intraclass correlation (ICC, single measure)		
Overall	0.904	0.680
Rest	0.902	0.615
Post-movement	0.879	0.725
Inter-rater agreement (Cohen's kappa)		
Overall	0.857	0.719
Rest	0.840	0.762
Post-movement	0.772	0.841
Internal consistency (Cronbach's alpha)		
Overall	0.950	0.810
Rest	0.766	0.762
Post-movement	0.797	0.841

As outlined in the table above, while the results of the present study were generally somewhat lower than those outlined by Atee et al. (2018), the present study demonstrated higher post-movement scores for internal consistency and inter-rater agreement. This further reiterates the suitability, reliability and validity of PainChek® for use as a semi-automated electronic pain assessment tool for people with dementia, as well as its multi-cultural suitability. The biggest differences in between the two studies was not necessarily in the findings, but in the way data were collected for some of the pain domains contained within the PainChek®. As outlined earlier, the activity domain was particularly challenging due to the care homes staff not having sufficient understanding and knowledge of changes in the activity domain and the researcher not having access to resident notes to verify behaviour changes. In addition to this, in previous studies, variability in the presence and severity of pain between the two tools and within specific pain domains has been identified (Neville & Ostini, 2014; Takai et al., 2010). For example, Neville & Ostini (2014) suggested that "item level internal consistency analysis consistently showed that the Abbey would be a more reliable

scale if the item ‘Physical Changes’ were omitted from the scale” (p. 803). In addition, in a study that developed and validated a Japanese version of the APS. variability in “physiological change” and “change in body language” domains were noted and Takai et al. (2010), concluding that cultural differences between Japanese and Australian older adults could explain some of the variability. The suggestions by Takai et al., (2010) and Neville & Ostini (2014) could therefore also be applied to this study.

6.4.2 Limitations

Some limitations of this study were present. The study aimed to be as pragmatic as possible. In this case, study pragmatism refers to being as realistic and practical as possible, to help replicate every day care home dynamics. For example, participants were not taken into a separate quiet room during pain assessments, as this would have been unrealistic and unsustainable for this particular care home. When residents show behaviour which could be associated with pain, the initial assessments are conducted in the communal areas of the care home. Because of this, the administration of PainChek® and APS was also completed in the communal areas, to replicate a realistic approach to pain assessment in care homes.

Therefore, some generalisability limitations are present as it is a single site study of one care home. Although participants with a variety of dementia diagnoses, levels of severity and a range pain diagnoses and conditions were recruited, some of the lower interrater agreement could be at least partly attributable to the recruitment of only one trained nurse. To explore whether interrater agreement increases or stays the same, multiple trained nurses across multiple care homes should be recruited to increase the overall generalisability and ecological validity of the findings.

In addition, the lack of knowledge regarding pain items in the activity domain of PainChek® highlights a cultural difference in terms of how UK based care homes are operated compared to AU based care homes. The four items in the activity pain domain: resisting care, prolonged resting, altered sleep and altered routine were items which the assessor (the researcher in this case) did not have sufficient information

about, without asking questions about the items in this pain domain per participant per assessment. Regardless of asking about whether any of the items were present prior to every assessment, it was noted that in majority of the cases, the care home staff were unsure of the answer. Once all data were collected, this was noticed by the researcher and the supervisory team and was further investigated.

The researcher was able to correct the data which were missing based on close investigation of internal care home records and correction of individual pain items for each assessment (as outlined in section 6.2.5 Statistical analysis and data correction). The correction of the data led to a further examination of why this issue has occurred. Upon speaking to the nurses in charge, it was discovered that there are several roles within the care home, and not all roles have the responsibility of knowing this kind of information. For example, while there is always a nurse in charge and at least one other qualified and registered nurse in the care home at any given time, majority of the staff are classed as homemakers or carers. Homemakers and carers have the responsibility of ensuring that residents are comfortable and cared for, however they do not need access to all medical records. If the homemakers and carers suspect a potentially concerning change of behaviour in a resident, they report this to the nurse in charge. This, therefore, means that all staff are not always aware of behaviours such as whether a resident has been resisting care, had altered sleeping or routine patter or prolonged resting.

Lastly, the author acknowledges that only limited data were gathered during this study. While gathering more data would have allowed for a more comprehensive understanding of observational pain assessment tools and other factors, it is also worthy to note that the data collected were in line with other validation and psychometric evaluation studies of observational pain assessment tools, such as studies by Atee et al., (2018), Husebo et al., (2010) or Warden et al., (2003) which collected measures focusing on reliability and validity of observational pain assessment tools. These mostly included comparisons and correlations between two or more observational tools, concurrent validity, intraclass correlations, inter-rater agreement and internal consistency. Future studies could also collect and analyse additional data including correlations between MMSE score, age and pain scores, predictive validity or sensitivity analysis. However, it would have been difficult to obtain

some data to investigate sensitivity of the observational tools. This is because a sensitivity analysis requires a golden measure, such as self-report of pain, to confirm whether pain is present. It is not possible to obtain this kind of data from participants living with moderate-to-severe dementia with high cognitive impairment who lack capacity.

6.4.3 Strengths

Strengths of this study include the length of visits and observation prior to data collection. This enabled the researcher to become familiar with the environment, procedures, dynamics, staff and residents. The observational period took place from September 2018 until January 2019, during which time the researcher was often involved in small activities with the residents, such as preparing tea and coffee, helping to feed residents during mealtime and talking with residents who were verbal. This enabled the researcher to collect highly ecological and organic data, as the participants reacted to the researcher with the same familiarity as they would have reacted to a staff member. This therefore not only increased the replicability of the conditions under which pain assessment would have been taken by nursing staff, but also the ability for the researcher to being able to differentiate painful and non-painful behaviours of participants which the nurse would have also been highly familiar with.

In addition, other strengths include reduction of bias by blinding the two assessors to each other's' pain scores during the data collection period, collecting the data in a real-world care home setting without interrupting flow of work or daily activities of the residents, which reiterates the appropriateness of the implication of PainChek® into care homes in the future. In addition, the psychometric qualities found within this study were similar to those previously outlined by Atee et al. (2018) demonstrating that this tool has a good potential for implementation and frequent use by care home staff in the UK. Lastly, as mentioned previously, the reasons for under-recognition and under-treatment of pain in people with dementia is complex, however, one of the contributing factors could be the suboptimal utilisation of observational pain assessment tools as a result of lack of time care home staff have to observe and record a pain assessment. Thus, implementation of an electronic observational pain assessment tool which not

only takes less time to use but also has the potential to be synchronised with local systems and upload assessments directly to patient profiles could be one of the first steps towards a more accurate and reliable pain assessment and subsequently treatment and management.

6.4.4 Implementation of findings

In terms of implementation, it is important to note the researcher experienced some issues with the automated facial recognition aspect in a black British participant. At times, the Facial Coding System failed to recognise the presence of face or gave a score of zero for the facial expression domain when it was clear that the participant was showing signs of facial expressions. This is not uncommon. An article published by Lohr (2018), was able to demonstrate that facial recognition is significantly less accurate in non-white populations. Lohr (2018) used facial recognition software to identify gender in lighter-skinned compared to darker-skinned individuals. Gender was misidentified in 1% of the lighter-skinned males and 7% in lighter-skinned females, compared to 12% of darker-skinned males and 35% of darker-skinned females.

These findings raised a broader question of fairness and accountability in artificial intelligence, especially given that many settings, services and providers are replacing paper-based procedures with electronic versions. Shortly after the limitation was discovered in this study, the researcher has discussed this with the developers of PainChek® who have subsequently started the process to improve the artificial intelligence algorithms of facial recognition across all ethnicities. Other interesting findings included a closer observation of two participants. One of the participants consistently scored higher pain scores at rest compared to immediately post-movement. This was seen in APS scores as well as PainChek® scores. The second participant, despite presence, painful diagnosis, several painful condition or severity of pain, would always smile whenever they were approached by the nurse, the researcher or any other staff member, relative or resident in the care home. The aforementioned two participants and their expression of painful behaviour will be further investigated and discussed in Case Studies (Chapter 7) later on in the thesis.

These findings, as part of the analysis and close investigation of individual raw data points, are very important for future implementation of the PainChek® for practice. Guidelines must be developed with these findings in mind, to ensure PainChek® is used correctly, especially in the UK care homes. One of the elements which is important to note, is the length of time it takes to administer the APS as well as the PainChek® and other observational pain assessment tools. The developers of the APS (Abbey et al., 2004) state that the tool takes no more than one minute to score, however there are no data provided to support this claim. This lack of evidence regarding length of time taken to administer the APS was also pointed out by (Herr et al., 2006). Furthermore, other observational pain assessment tools can take much longer to complete. For example, the developers of the Pain Assessment in Dementing Elderly (PADE) state that the administration of this tool requires approximately 5-10 minutes to complete (Villanueva et al., 2003), however Zwakhalen, Hamers, Huijer Abu-Saad, & Berger (2006) questioned this, and suggest that given the complexity of the tool, it probably takes longer.

The Discomfort in Dementia of the Alzheimer's Type (DS-DAT) requires waiting 15 minutes after a patient has started to show behaviours associated with discomfort before the tool can be administered, with the completion of the assessment taking additional 5 minutes (Herr et al., 2006). The time it requires to observe and complete observational pain assessment tools can be considered lengthy, especially in a busy environment such as nursing care homes. The automated facial expression recognition technology of the PainChek® has only taken three seconds to complete. The rest of the assessment is manual, where the assessor is required to indicate the presence of pain behaviour items within the remaining 5 pain domains. From the researcher's experience of the present study, the PainChek® took approximately 1-2 minutes to complete, however the exact length of time was not measured. Considering the time required for assessment completion of other observational pain assessment tools, such as the aforementioned DS-DAT or PADE, the PainChek® is much faster to complete, which is a noteworthy feasibility advantage especially for care home nurses who are overworked and often have lack of time to deliver person-centred care (Smythe, Jenkins, Galant-Miecznikowska, Bentham, & Oyebode, 2017). Additionally, there are several factors, such as the potential effect of pain acceptance (McCracken

& Iverson, 2001) or a “freezing state” which should be considered when conducting validation studies such as this one. These factors are further discussed in Chapter 8.

Lastly, due to the scope of this PhD, there were some elements which were not investigated as part of this research but would be interesting to investigate in the future. For example, further analyses and interpretations of how much type of dementia, type of pain diagnosis or severity of cognitive impairment affects pain assessment and pain assessment score, should be investigated in the future. This could allow for further knowledge and understanding of the types of pain behaviours expressed and severity of pain by individuals with mild compared to moderate or severe cognitive impairment, or individuals with vascular dementia compared to Alzheimer’s Disease. In addition, future studies investigating validity, reliability or psychometric qualities in general, could also offer further investigation into inter-subject and intra-subject correlations, as well as other cross-sectional analyses, to examine whether these factors affect the results, to what extent and what the implications of this are.

However, neither of the two suggestions stated above were not the focus of this study. Instead, the scope and focus was to further validate and investigate the validity and reliability of PainChek® in a country with different care home dynamics, systems and culture. The results, in this case, were strengthened by the person-centred aspect which was achieved by the observation period prior to data collection, which ensured familiarity with dynamics, schedules, staff and most importantly personalities and behaviours of care home residents.

6.5 Conclusion

In conclusion, this study has demonstrated in the UK population living with dementia, that PainChek® is a highly sensitive tool with regard to detecting pain, which saves time and reduces risk of human bias and error. This tool has the potential to empower all caregivers to accurately assess, treat and manage pain in care homes. PainChek® supports healthcare providers to improve quality of life in the population with dementia

and has the potential to be developed further for the use of caregivers at home environment. Furthermore, some results could be explained by participants who would usually be deemed as outliers. These outliers are participants who do not fit in with the norm and distribution of the rest of the raw data and are often removed and not considered for analysis. In this case, the data from the participants who did not fit in with the norm were kept in the data set and analysed to provide a more organic data set, which represents the everyday world. Three participants which would have been deemed as outliers are further investigated and discussed in Chapter 7 as case studies, to enable the researcher to understand pain in dementia, and atypical behaviour in more depth.

7 Chapter Seven – Case Studies

7.1 Introduction and background

As discovered in the Systematic Review (Chapter 4) a variety observational pain assessment tools as are available to assess pain in people living with dementia. Researchers continue to develop new tools and improve the ones which are already available. For example, the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) was originally developed and validated by Fuchs-Lacelle & Hadjistavropoulos in 2004 and later a new version named PACSLAC-II has been developed by Chan (2013). Additionally, some pain assessment tools were amended and further developed based on results from initial pilot studies (Feldt, 2000), others were further developed as a result of initial evaluation of psychometric properties (Cervo et al., 2009). Some pain assessment tools such as the Doloplus® or the Abbey Pain Scale were also translated to a variety of languages (Pickering et al., 2010; Takai et al., 2010). Yet, regardless of these developments and further validations, high number of people with dementia still appear to experience pain daily (Husebo, Ballard, & Aarsland, 2011).

Despite 25 years of research on dementia, there is still a gap in our knowledge when it comes to recognising, assessing, treating and managing pain, which is detrimental to those dying with dementia. An overwhelming majority of individuals with dementia experience weakness, fatigue, disorientation, loss of appetite, anxiety, tension and moderate to severe pain two days before death (Pinzon et al., 2013). To reduce the number of individuals with dementia at end-of-life who are weak, fatigued and in pain, it is crucial that, with the help of large-scale studies and case studies, evidence-based guidelines and practice are developed to prevent distress and further understand how the quality of life can be increased while pain is decreased. As discussed in Chapter 2, quality of life is not only difficult to measure in people living with dementia due to their lack of ability to communicate because of cognitive deterioration, but also many of the scales used to measure quality of life are largely only used for research.

It is unclear why after over 25 years of research into pain and dementia, pain is still so under-recognised and undertreated (Sengstaken & King, 1993; Cunningham et al., 2010), especially as access to pain management has been declared as a fundamental human right in 2011 (International Pain Summit of the International Association for the Study of Pain, 2011). Failure to detect pain in individuals due to individual differences and variability in pain expressions has been outlined as one of the limitations to accurate and reliable pain recognition, assessment, treatment and management in people living with dementia (Peisah et al., 2014). In addition, as discussed earlier, failure to provide appropriate pain treatment and management breaches fundamental human rights (Somerville, 2001), which further reiterates the pressing need to not only develop accurate and appropriate observational pain assessment tools, but also to continue considering how individual differences, subjectivity of assessors, bias, human error or other factors might impact pain assessment.

In their critical literature review, Birch & Draper (2008) reiterate the urgent need to improve care for older people with severe dementia to ensure quality and equality for all individuals in end-of-life stage of dementia. This is further reiterated by concerning research conducted by Peisah et al. (2014) who demonstrated that timing and frequency of pain assessment in people with dementia living in care homes is often more regulatory-driven (e.g. pain assessment on admission, or in the run-up to accreditation) than patient-driven (e.g. when the person appears to be in pain). The frequency of use of the observational pain assessment was approximately every three, six or twelve months, rather than as often as required. The same study also reported that in one case, the pain assessment tool was used to convince a GP to prescribe potentially addictive drugs, rather than to use it as effective pain management.

One of the issues for studies with a smaller sample size could be its generalisability, especially for studies such as clinical trials (Faber & Fonseca, 2014) especially as case studies have often been criticised for lack of generalisability (Tsang, 2013). Being able to generalise findings to a broader population or cohort usually helps with the understanding of behaviours and phenomena, and the applications of the results to settings and populations other than those which were originally tested. However, in some larger-scale studies, the participants who do not fit in with the norm of results are usually declared as outliers and therefore either removed from the data set prior

to analysis or somewhat manipulated. While data manipulation to an extent is usually an accepted way of cleaning outliers, analysing and reporting results, it is also a cause for concern. This is because it is possible that those participants and data sets which are deemed as outliers, could be cases of individuals with dementia who simply show different pain behaviours than the rest of the participants. Declaring individuals whose results do not fit in with the rest as outliers and not investigating their data in more depth, could prevent us from truly understanding how to effectively and accurately assess and treat pain in all individuals living with dementia.

During the data collection of the validation study, the main researcher has noticed behaviours, which were unexpected. Upon further investigation, it was clear that three out of the twenty-two participants were showing behaviours, which have not been discussed or considered in previous research. While the three participants continued to be part of the validation study, they were observed in more depth by the researcher and the nurse, and any unusual behaviour was noted. The observation of the three participants led the main researcher to build case studies, to demonstrate how some preconceived assumptions and expectations about what painful behaviour should look like in dementia does not always fit in with the norm.

The aim of this chapter is to highlight the importance of investigating individual differences in people living with dementia, and the need to consider those who do not fit in with the norm and the impact of this on recognition, assessment, treatment and management of pain.

The objectives were:

a) To explore individual differences within people living with dementia and their atypical painful behaviour
b) To offer possible solutions to enhance more accurate pain assessment in individuals presenting atypical pain behaviours

7.2 Method

Three participants were selected by the researcher of this thesis, during data collection for Validation of PainChek® study (Chapter 6). During the 16-week data collection, the three participants have demonstrated behaviours which were not expected and differed from the behaviours demonstrated by the rest of the participants or previous literature. As discussed in Chapter 3 case studies are often criticised for lacking rigour and objectivity (Rowley, 2002), however, they can be very useful at addressing and understanding specific issues which need to be investigated further (Noor, 2008). In this case, the selected individuals in three case studies were considered to demonstrate atypical pain behaviour and were therefore deemed appropriate for further investigation. Atypical behaviours refer to expressions of pain behaviours which are not commonly reported within the six pain domain categories, such as those outlined by Alzheimer Society (2017).

The three chosen participants have been observed closely as part of the validation study over the full 16-week period. All three participants were female, had a diagnosis of dementia (66.7% Alzheimer's disease and 33.3% mixed dementia) and had a pain condition diagnosis or presence of due to recent injury or fall. All three participants scored zero on the Mini-Mental State Examination (MMSE) scale the end of the 16-week data collection stage, indicating severe cognitive impairment.

Consent was given, allowing the researched of this study to access relevant care records during the data collection period. In addition to making notes of behaviours, relevant information such as diagnoses and some medications were noted, to help build and understand each case study. To comply with GDPR and ensure participant confidentiality and anonymity, all participants have been given pseudonyms, which they are referred to in the case studies.

7.3 Case study 1: Margaret: Perceived comfort

7.3.1 Case study 1: Background information

The participant in the first case study has been given the pseudonym Margaret. At the time of the data collection, Margaret was in the advanced stages of dementia – Alzheimer's disease and therefore was unable to communicate verbally. A few years ago, Margaret had a fall which resulted in a right hip fracture and a hip replacement. Margaret has shown signs of dementia before the fall, but since the fall, Margaret's mobility has slowly deteriorated. A few months ago, Margaret was able to walk around the care home with the support of a walking frame and the occasional assistance when getting up from her bed; however, she is no longer mobile. Margaret was only able to stand up with the assistance of two caregivers, but over the past few months, she struggled with this task more and more. She is now mostly hoisted to help the transfer process from bed to a wheelchair, but she can stand up to transfer from a chair to a wheelchair.

Margaret had high blood pressure, is at high risk of pressure ulcers and is at high risk of falls. Margaret is medicated with Fybogel, Lansoprazole (30 mg), Colecalciferol (800 units), PRN paracetamol (20 ml) and Trazodone (50 mg). Margaret receives paracetamol to help her treat and manage pain when required. During a discussion with one of the nurses in the care home, the nurse stated that Margaret needs stronger and more effective painkillers, however, the GP does not agree with this as Margaret was often in bed or eating during the visit from the GP, therefore the GP often does not see Margaret's painful behaviours which usually manifest as restlessness, rocking and tense facial expression.

Margaret spends most of her day in a communal area watching TV. She sits on a pressure cushion at all times to help reduce the risk of pressure ulcers. When approached, Margaret will often try to greet the person who has approached her, but it is very clear that she struggles to put words and sentences together. Occasionally,

she will say simple words such as “hello” or even statements such as “hello my darling”.

Margaret was very restless and often rocked back and forth in her chair. In addition to the rocking, she constantly crossed and uncrossed her left leg over her right leg. She often reached her hand out when approached and leant forward grabbing the arms of her chair as if she was about to get up from the chair. She repeated this motion, along with the restless legs, at all times, until she has been transferred to a wheelchair with her feet resting on footrests or when she is in bed. When resting in a chair, Margaret often leant to the left; taking the pressure off her previously fractured hip. Her face very often looked tense or distressed and she often sighed and take deep breaths.

During the Validation of PainChek® study (Chapter 6), Margaret was approached once or twice a week and had her pain assessed during rest and immediately post-movement. Margaret’s resting scores were often much higher than her post-movement scores. For example, Margaret’s mean PainChek® score at rest was 8.76 indicating mild pain and her mean APS score at rest was 5.17 (mild pain), whereas the mean post-movement PainChek® score was 6.59 (none to mild pain) and 4 for APS (mild pain). At the start of the data collection period, Margaret was still able to take a few steps when assisted, compared to the end of the data collection period where Margaret was only able to stand up (assisted). The cause of this deterioration was unknown, but it was attributed to the natural progression of dementia. Regardless of whether the movement element of the study involved Margaret taking a few steps or just standing up and being repositioned back into the chair, Margaret consistently scored higher for resting pain assessment across the APS and the PainChek®. The scores from both tools demonstrated the top end of moderate pain during rest, whereas immediately post-movement the pain scores dropped down to mild or low end of the moderate pain category. While she struggled to stand up and did demonstrate some behaviours associated with pain such as louder whimpering and sighing, after sitting back down she appeared much happier and settled, and her restlessness would stop for approximately 20 minutes.

7.3.2 Case study 1: Key problems

The key problem in Margaret's case is that there is an unmet need for a comfortable rest. As it is clear from Margaret's case, previous research has also recognised that one of the major issues is the communication and trust between the care home nurses and getting the GP to recognise presence and severity of pain in people with dementia (Gregory, 2011). In one qualitative study the participants expressed very concerning issues regarding interactions between nursing and medical staff. One participant stated:

"Every now and again the GP does not want to listen when we really do believe that the person is in pain." (Peisah et al., 2014, p. 1770).

The quotation above not only reiterates the need for better communication and understanding between the health care professionals, but also the need for interprofessional education and collaboration which is patient-driven and focuses on person-centred care (Baker et al., 2008). The key focus of a collective health professional team should be to respect all dementia care roles and address the individual needs, to ultimately improve quality of life at the end-of-life stages of dementia.

7.3.3 Case study 1: Proposed solutions

Interprofessional learning in practice and improved collaboration and communication between health care professional has been a priority for some time in the UK (Forman & Nyatanga, 1999). Although since the work published by Forman & Nyatanga in 1999, research and recommendation for practice in health and social care have been outlined and implemented; there is still a clear need for development and implementation in this area as demonstrated by the case study above. One of the suggestions from investigating Margaret's case, could be that there is a lack of Interprofessional communication and trust between care home staff and GPs, which

could be one of the issues which negatively impact pain treatment and management. The World Alzheimer Report (Martin et al., 2015) recommended the development of a dementia care workforce, which advises that the dementia care workforce needs to be adequately trained to provide person-centred care. One of the ways in which this can be implemented is through the aforementioned interprofessional learning and education.

In addition, interprofessional learning and education focuses on training health care professionals to work together as a team, to address individual needs and enhance person-centred care. The understanding of importance of all dementia care roles between all health care professionals can lead to better collaboration and delivery of higher care quality overall. A study by Cartwright, Franklin, Forman, & Freegard (2015) investigated this aspect of dementia care further. The researchers successfully developed and implemented a better practice for dementia, through the development and use of online-based interprofessional education case study. The participants in this study were presented with new information about a fictional client every week for four weeks, which allowed them to reflect on previous information over time. The findings have shown that through interprofessional education in dementia care, the participants have recognised the value in effective interprofessional dementia care practice, to improve the quality of person-centred care.

"Personally, I support the discourse that caring for an older person with complex and interactive health care needs is best achieved when the knowledge and skills of various health disciplines are shared and integrated." (Cartwright et al., 2015, p. 92).

However, while the quote above further reiterates the importance of interprofessional education in practice, it is also important to note that implementing interprofessional education and learning as part of training for care home nurses needs to be considered carefully, as this alone would not resolve the issue completely. Nonetheless, implementing this could enhance trust between professionals. If the GP listened to the nurses in Margaret's case, perhaps Margaret's pain would be treated and managed more appropriately. This demonstrates the need for more holistic care to be taken into consideration. While assessment instruments are an excellent way to guide and

support health professionals towards providing better care, it is just as important to consider the individual's history and other aspects of their behaviour.

7.4 Case study 2: Doris: The smile of pain

7.4.1 Case study 2: Background information

The participant in the second case study is called Doris. Doris has been diagnosed with Alzheimer's disease several years ago but has been able to live at home independently or with occasional help from her relatives until approximately six months ago, when she was transferred to a local care home. Doris currently resides in the section of the care home which focuses on caring for individuals with moderate to severe stages of dementia.

Doris is non-verbal, and in the validation study in Chapter 6, her vocalisation domain was always represented by a score of zero by both pain assessment tools. A score of zero demonstrates that the vocalisation behaviour (e.g. whimpering, sighing, loud talk, crying) was not present. Although Doris sometimes needed assistance when standing up from a chair or a bed, she was mobile and often wandered around the care home unassisted. Across all pain domains, Doris' score usually indicated no pain or mild pain across the data collection period. For example, Doris' mean score at rest was 2.75 (none to mild pain) for APS and 4.17 (no pain) for PainChek®, APS score of 3.38 (mild pain) and PainChek® score of 6.12 (none to mild pain) for post-movement.

Doris suffered from chronic oedema in her legs, and she was also prone to pressure sores and at an increased risk of falls. She was medicated with Citalopram and PRN paracetamol. Doris has recently lost her balance while walking around the care home, which has resulted in a fall. Doris was taken to the hospital immediately, but luckily, apart from some minor bruising, she did not sustain any major injuries such as

fractures. Since the fall, Doris has been a lot more hesitant to wander around the care home and started spending more time sitting on a sofa or at a dining table.

Regardless of the time of the day, when approached, Doris always smiled. She smiled while eating her breakfast, during an activity, immediately after she has been woken up, and even when she was otherwise clearly in discomfort. Following the recent fall, Doris was not as confident wandering around the home as she was prior to the fall. She needed assistance in getting up from a chair or transferring from one room to another more often than before. She would often reach her hand out to hold onto someone while walking. Although Doris only sustained minor injuries from the fall, she was clearly in pain. She often sat abnormally; leaning to one side, her sleeping pattern had changed and her appetite decreased significantly. When observed from a distance, Doris' facial expression often indicated moderate pain. Her eyelids were tightening, eyes closing; she was often frowning and looked very tense in general. Despite this, every time she was approached, regardless of whether the person who has approached her was another resident, a nurse, the researcher or visitors, she always smiled and continued to smile until the person left.

7.4.2 Case study 2: Key problems

The key problem in Doris' case study is not the fact that she smiled when approached. The key problem is that a smile is often seen to represent happiness or a positive effect (Ekman & Friesen, 1982). A smiling individual might come across pain-free, but this is often not the case. The smile response when experiencing pain is not uncommon, nearly a third of participants in a study conducted by Kunz, Prkachin, & Lautenbacher (2009) have responded with a smile when approached regardless of the pain severity experienced at the time of the study.

There are several speculations regarding the smile of pain. Some studies suggest that smiling when experiencing pain could be a way to self-regulate the distress associated with pain or other experiences (Ansfield, 2007). In addition to this, in a study conducted

by Zweyer, Velker, & Ruch (2004) the effect of cheerfulness, exhilaration and humour on pain tolerance were investigated further. In their study, pain was induced in participants using a cold pressor while they were watching a comedy film. Participants were randomly assigned into one of three conditions; 1) cheerfulness (getting into a cheerful mood without laughing, 2) exhilaration (smiling and/or laughing extensively) and 3) humour production (producing humorous commentary to the comedy film shown). The results have demonstrated that pain tolerance was increased in across all three conditions. Although due to Doris' severe cognitive impairment, this is only somewhat applicable to this case study, it is interesting to note that a smile can help with self-regulation of pain. That being said, it must be stressed that regardless of increased pain tolerance during exhilaration, cheerfulness and humour, the experienced pain is still present, showing that individuals are not pain-free if they are smiling. Therefore, appropriate treatment and management of present pain is still needed.

Another explanation of this behaviour could be regression back to childlike or primitive behaviour. As a result of the deterioration of brain cells and tissue in dementia, the trajectory of life reverses and a degree of regression may occur (Ng, 2009). Doris' cry vocalisation always stopped as soon as a person had approached her. Perhaps Doris' cry was a way to attract attention and company.

7.4.3 Case study 2: Proposed solutions

Similarly to Margaret's case in Case Study 1, one of the issues in Doris' case is the need for better education about dementia and pain behaviour in general. A study by Zwakhalen et al. (2007) indicated that nurses in dementia care facilities have shown deficits regarding pain assessment, management and treatment for individuals living with dementia. Such deficit in knowledge can be detrimental in the quality of delivered care in dementia. Further to this, dementia care nurses have reported that some of the barriers to delivering high-quality care is lack of time and staffing (Fessey, 2007). The staffing issue has also been highlighted by participants in a qualitative study conducted

by Kupeli et al. (2018) where the lack of staffing has been attributed to finance saving measures within care homes. Nonetheless, lack of time and staffing highlights a barrier to high-quality dementia care. This is concerning, as nurses are often faced with a situation where they have to prioritise care to meet the needs and demands of individuals. This could prevent nurses from understanding Doris' behaviour of pain, especially if their time does not permit them to spend time to learn more about Doris' smile of pain.

Therefore, there could be several proposed solutions to this problem including re-thinking funding, staffing and workload as well as implementation of training which teaches care home nurses about atypical behaviours such as those in this case. This applies to several aspects, including education about smile of pain or other uncommon behaviours. If the nurses in dementia care have the knowledge of atypical pain behaviours and the time to observe residents carefully, this could lead to a higher quality of holistic care and potentially mitigate some of the pain assessment, management and treatment issues. In terms of this case study, less workload and more time could allow the care home staff to discuss Doris' pain levels and her smile regardless of pain severity with relatives could prompt the relatives to think about whether this is usual or unusual behaviour for Doris.

The prior knowledge about pain presence, severity and pain associated behaviour combined with the discussions with the relatives is, therefore, necessary to ensure the best possible quality of care for those living with dementia (Hirst, Blake, & Lane, 2003). However, there could be a simple solution. Barry, Parsons, Passmore, & Hughes (2012) have conducted a study into knowledge and attitudes towards the treatment and management of pain in individuals living with dementia and found that education and a higher level of knowledge was a significant part to play in the successful management of pain in dementia.

7.5 Case study 3: Agnes: The cry for help and attention

7.5.1 Case study 3: Background information

The participant in the final study is called Agnes. Agnes was an 84-year-old lady, diagnosed with moderate to severe mixed dementia (Alzheimer's and Vascular), who had osteoporosis and arthritis in her knees, and has lived at the care home for just over a year. Agnes required some assistance getting up from bed in the morning, but otherwise, she was able to stand up and walk around the care home without any support. Agnes was somewhat verbal; she was able to answer "yes" or "no" to simple questions such as "would you like a cup of tea" or "are you hungry?" but she struggled to answer questions which were more complex or open-ended.

At times, Agnes started telling a story but often got stuck halfway through a sentence, repeating the same word over and over again. If Agnes was having a good day, in a similar way to Doris, she always smiled when approached, laugh at stories, danced to music if the radio was on and even whistled a tune. She took pride in the colours of the clothes she was wearing, often pointing to an item of clothing and sometimes correctly identifying and verbally confirming the colour. When she named the colour of her clothes correctly, the nurses often praised her by saying "that's right Agnes, your jumper is pink". Agnes was very pleased by this and would proceed to repeat the colour of her jumper continuously for some time.

When Agnes was having a bad day, she isolated herself to a corner of a communal room or sought a quieter place to sit alone. Her facial expressions very clearly indicated unhappiness, distress and her pain behaviours were very animated. She guarded her knees with her hands to protect them, as they were often the cause of her pain. She also shivered and rocked back and forth in a chair. The most prevalent pain associated behaviour she demonstrated was vocalisation, specifically crying noises.

Agnes made crying noises almost at all times. She made crying noises while wandering around the care home, sitting down, watching TV, while she was seated around a table waiting for her food to be served. She sometimes made crying noises during trying to tell a story or even while she ate food. An important note to keep in mind is that while Agnes made crying noises during majority of the time she was awake, there were never any tears or any other symptoms associated with crying other than several facial micro-expressions. Agnes' mean score at rest was 6.50 (none to mild pain) for PainChek® and 3.94 (mild pain) for APS and her post-movement mean scores were 7.54 (mild pain) for PainChek® and 4.31 (mild pain) for APS.

Agnes was prescribed PRN paracetamol to help her manage osteoporosis and arthritis in her knees but took no other pain medication. She also took antidepressants in form of Citalopram. Other than the pain diagnoses, dementia and unusual vocalisation, Agnes did not portray any other behaviours or symptoms which were of concern. In a similar way to Doris, when Agnes was approached, her behaviour in terms of vocalisation changed. She stopped making crying noises almost immediately upon being approached. Sometimes she resumed these while the person who had approached her was present, and other times the vocalisation did not resume until the person has left.

7.5.2 Case study 3: Key problems

From the observational pain assessment perspective, Agnes' vocalisation can be very misleading and confusing. The nurses in the care home often mentioned that Agnes' vocalisation is just her way to attract some attention and spend time with some of the nurses or staff, while other nurses think that Agnes' vocalisation is a cry for help, possibly out of pain. As mentioned earlier, Agnes' pain presence and severity usually indicated no pain or very mild pain. Other than the vocalisation, she only demonstrated a couple of other pain-related behaviours, such as knee guarding and occasional rocking or wandering. When observing Agnes the assessors of PainChek® and Abbey Pain Scale would often notice this vocalisation and mark it

down as an indicator of painful behaviour. At times, this would be the only non-facial expression pain indicator that would score a point on both scales. As mentioned above, Agnes' vocalisation would often stop when approached. Additionally, neither the Abbey Pain Scale nor the PainChek® were able to pick up on facial expressions which are indicative of pain.

The key problem in Agnes' case is the debate about whether her vocalisation is simply just a 'cry for attention'. In the past Hudson (2007) speculated whether the cry of dementia is attention-seeking, a plea for someone to attend the person's needs, or whether this behaviour has another explanation. However, due to the nature of the condition, it is difficult to measure and investigate the cry of dementia in more depth, and therefore there is a lack of research conducted into this area of research. Thus, it is difficult to pinpoint whether the crying behaviour is attention-seeking or whether there is an underlying and potentially painful experience which needs to be targeted correctly, treated and managed appropriately.

Although in most cases, Agnes is able to indicate how she feels by answering simple questions with "yes" or "no", majority of times when she has been asked whether she is in any pain, she laughs, makes a crying sound and occasionally answers yes or no, but it is difficult to know whether she understood the question and understands the concept of pain, or whether her response is somewhat automatic and intuitive. In extreme cases, studies reported that nurses are more likely to show frustration and anger towards individuals with vocally disruptive behaviour, and therefore distancing themselves from the residents with these vocal behaviours (Draper et al., 2000), which can result in undertreatment of the residents with dementia (Jeandel, 2004 as cited in von Gunten et al., 2017). The findings reported in these studies are a cause for major concern and should be addressed with urgency to prevent maltreatment of individuals with dementia and premature death.

7.5.3 Case study 3: Proposed solutions

The proposed solution focuses on better pain recognition and analysis and increased focus on atypical vocalisation clues, in Agnes' case crying noises. A study by Nagaratnam, Patel, & Whelan (2003) investigated atypical noise making in people with dementia from a biological perspective. Their case studies included individuals with dementia with persistent screaming, perseverative vocalisation, continues chattering, muttering, singing or humming and individuals who swear, grunt and make bizarre noises. Atypical noises are not unusual for individuals' with dementia, but they are usually more common in the later stages of dementia. In the article by Nagaratnam et al. (2003), one of their case studies included a female participant who, similarly to Agnes, often made crying noises, mutters unintelligibly and her ability to express herself is significantly reduced. After the female participant in this paper has passed away, a CT scan has revealed that she had generalised cerebral atrophy. The article by Nagaratnam et al. (2003) recommends the use of antipsychotics and antidepressants to manage vocally disruptive behaviour. However, this might not be the most appropriate solution, as the treatment should be person-centred and reflect their needs. Unnecessary use of antidepressants in people with dementia increases risk of falls and fractures (Wei, Simoni-Wastila, Lucas, & Brandt, 2016) whereas the unnecessary use of antipsychotics in people with dementia increases the likelihood of premature death (Department of Health, 2009; Gill et al., 2007). Thus, the solution of the vocally disruptive behaviour should focus on identifying the underlying cause of the behaviour and resolving it rather than medicating the individuals with dementia to stop the vocalisation without identifying the problem first. Distressful behaviours such as crying, are likely to be treated with antipsychotics or antidepressants.

7.6 Discussion

The findings of this case study further highlighted behaviours expressed by people living with dementia which are often not reported and may therefore hinder accurate

pain assessment. The behaviours expressed by the individuals in the three case studies were not described or listed within the six pain domains outlined by the AGS (2002) and therefore reiterate the importance of considering individual differences especially in people living with dementia. In addition, the results of this case study further indicated the need for further investigation and research into the factors which hinder appropriate pain treatment and management in people living with dementia. While the issue of accurate pain treatment and management is more complex and goes beyond simply ensuring correct and accurate use of observational pain assessment tools, this may be one of the factors contributing towards this issue. The three cases have independently highlighted that there may be a need for better interprofessional communication and learning between care home staff and GPs, however it has also been acknowledged that there may also been structural factors which have can have an impact on pain assessment, treatment and management. For example, if the GPs are overburdened with other responsibilities and tasks, it might be difficult to make a longer visit where an observation of the care home residents can take place.

In the introduction and background section of this chapter, some of Peisah et al. (2014) findings were outlined. The results suggested a lack of frequent pain assessments in care homes and the nature of pain assessments being regulatory driven rather than patient driven. In addition to this, another issue highlighted within this case study was the lack of time and high levels of workload care home staff are faced with, as well as lack of staffing within care homes. This was also reported by Kupeli et al. (2018) who highlighted a profit-drive approach rather than an optimal care driven approach in care homes, resulting in inappropriately low levels of staff within care homes. While these are fairly well reported factors and barriers to high quality holistic care, this case study tried to answer the ”how” and “why” questions. The answers to these questions could inform future practice and changes to policies. For example, continuing to reiterate how lack of time, funding, education and workload in care homes can lead to missed observations of behaviours which are indicative of pain could continue to highlight the issues and the need for implementations of changes in care homes.

One of the concerning findings in this study, was that pain assessment was not always used to observe and assess pain when an individual showed pain behaviours. This

could be explained by a couple of possible factors. Firstly, this could simply be down to the lack of time and workload previously mentioned by the nurses resulting in not having enough time to observe and record a pain assessment of each individual every time their behaviour indicates presence of pain. Secondly, it could be argued that in smaller nursing facilities where nurses are very familiar and can distinguish between painful and pain-free behaviour in residents whom they are caring for, the pain assessment tools are not used as frequently as they should be.

Nurses have reported familiarity with painful and pain-free behaviours in residents (Liu, 2013), which therefore could explain the lack of pain assessments. Familiarity, however, does not warrant accurate pain recognition and observation. If an individual with dementia experiences new type of pain, the behaviour might not reflect the usual pain behaviour, therefore hindering appropriate pain recognition. In addition to this, all pain assessment should be appropriately recorded in case they are needed as part of evidence for GP visits.

In terms of the three case studies, the nurse who collected Abbey Pain Scale pain assessment scores recognised pain at rest in Margaret and understood that a smile from Doris did not mean pain-free experience. However, the severity of Margaret's and Doris' pain would need to be further investigated and monitored by an observational pain assessment tool such as PainChek®. This would also allow ongoing documentation of the presence and severity of pain, which could then be given to a healthcare professional such as a GP for review of pain medication and dose.

Pain recognition and assessment is the baseline of appropriate pain treatment and management. While there are tools which help nurses identify and assess presence and severity of pain, the type and dose of pain-relieving medication is ultimately down to recommendation and prescription from a health professional such as a GP. If an individual with dementia does not demonstrate a usual patter in pain behaviour, it might be difficult to demonstrate the presence and severity of pain to a GP. The lack of evidence of presence and severity of pain and the interaction between a nurse and a GP can lead to inappropriate and insufficient pain treatment and management. Findings from Peisah et al. (2014) demonstrated that sometimes GPs refuse to listen to nurses regarding the presence and severity of pain in certain residents. This was

also clear from Margaret's case. When the GP visits, Margaret is often in bed or has just been transferred from a bed to a chair, which therefore prevents the GP to see Margaret's atypical painful behaviour. The GP would have to observe Margaret for a significant amount of time after she has settled in her chair and has rested to be able to notice some of Margaret's painful behaviours. Even then, as the literature suggests, this might not be enough to change the pain management plan or increase the dose of prescription.

In addition, in a study similar to that of Peisah et al. (2014), it was reported that a lack of trust or knowledge of pain behaviours between care home nurses and GPs can hinder pain management and treatment (Kupeli et al., 2018). In the qualitative study conducted by Kupeli et al. (2018) one of the quotes demonstrated potential trust issues between a GP and a care home manager:

"I want something for pain relief but she won't take anything orally because she's refusing all medication', 'well if she says not in pain from your pain assessment then I can't prescribe something', 'yes but looking at her, she is in pain but she's one of these people that sort of keeps quiet', so it's more about, I suppose people trusting you (Care Home Manager)." (Kupeli et al., 2018, p.171)

These findings are highly concerning and may be improved with implementation of interprofessional education and learning. In addition, the study by Kupeli et al. (2018) also highlighted under-staffing issues and overworked care home staff which may all collectively contribute to lack of appropriate pain treatment and management. As outlined in Chapter 7, a study by Cartwright, Franklin, Forman, & Freegard, (2015) has demonstrated that the inclusion of interprofessional education activities within current undergraduate curricula can improve quality of collaborative person-centred dementia care. Thus, the collaborative teamwork between care home nurses and GPs could be improved by implementing interprofessional education into nursing home practice. However, it is also important to note that the issues faced when assessing, treating and managing pain is complex and therefore interprofessional education and learning alone cannot mitigate these issues. Nonetheless, implementing better interprofessional education and learning may enhance the trust between care home staff and GPs.

Most people with dementia regularly experience and die in pain, causing higher levels of distress in their final days. Pain is not always easy to recognise, and it might be difficult to prove to GPs that it exists. It is critical that more funding and time, less workload and better communication between nurses and clinical staff amongst other factors, are further investigated and that the findings from studies and case studies such as this one are used as evidence towards a start of policy and regulatory change in care homes. Moreover, there cannot be an effective treatment for all individuals if we forget to consider those who do not fit the norm or deviate from typical painful behaviour. Accurate assessment of pain using pain assessment tools must be used frequently and with patient-driven intentions to help recognise, assess, treat and manage pain in individuals with dementia.

The biological perspective from Nagaratnam et al. (2003) outlined in Agnes' case study was worth noting. Dementia is still somewhat misunderstood, with large biological gaps in understanding of onset, development and determination of the brain due to dementia. The case study in Nagaratnam's paper stated that the participant who has similar vocal symptoms to dementia was found to have cerebral atrophy, which was not unexpected due to the nature of the condition. Further CT scans revealed that cerebral atrophy was also found in participants with dementia who showed other atypical vocal behaviours, such as persistent screaming, chattering and 'bizarre noise-making'. While this potentially links some of the behaviours with the progress and deterioration of brain tissue in dementia, this still does not help us understand whether the noise-making is a result of cerebral atrophy or whether there is another underlying cause for this entirely. A cause of concern is the recommended management of noise making and other disruptive behaviour. In the past, researchers recommend the use of pharmacological treatment (Goldberg & Goldberg, 1996), specifically antipsychotic medication (Kopala & Honer, 1997) and antidepressants (Pasion & Kirby, 1993). While these research reports regarding the use of antipsychotics and antidepressants for people with dementia are fairly outdated, the use of antipsychotics to manage psychological ad behaviour symptoms of dementia were reported as late as 2009 (NHS, 2009). In addition, newer studies highlight potential risks and benefits of administering antipsychotics and only recommend their administration for severe symptoms that have failed to respond to non-pharmacological treatments and approaches (Tampi et al., 2016).

While unusual and persistent vocalisation behaviours from individuals with dementia can be distressing and upsetting to other residents, visitors and nurses working in the care homes, it is important to reiterate that residents should not be treated with antipsychotics or antidepressants unless absolutely necessary, until the underlying cause behind the noise making is identified. In Agnes' case, the crying noises can be associated with the pain she is experiencing in her knees or another underlying issues which needs to be investigated and identified.

Further to the literature outlined above and the literature outlined in Agnes' case study, a systematic review was conducted to investigate vocally disruptive behaviour in the older people (von Gunten et al., 2017). The systematic review considered studies, which previously investigated individuals with vocally disruptive behaviours such as crying noises. One of the findings in this systematic review were the perceived consequences of disruptive behaviours from the papers included. It seemed that the major consequences that the articles in this systematic review focused on were the disruption of the vocal behaviour on other residents, informal caregivers and formal caregivers. This is somewhat concerning as the focus of the vocally disruptive behaviour could have been on the underlying causation and how to treat and manage it. Nonetheless, the systematic review also reported suggested treatment options for individuals with vocally disruptive behaviours. While there seemed to be a fairly heavy focus on biological treatment in terms of antipsychotics, antidepressants and sedatives, other treatment options were also investigated. Psychological interventions such as those focusing on the resident's needs which includes music therapy, guided imagery, fantasy and sensory stimulation have been used and have demonstrated a reduction in verbally disruptive behaviours (Bédard, Landreville, Voyer, Verreault, & Vézina, 2011; Cohen-Mansfield & Werner, 1997).

The researcher of this study recognises some limitations. The key limitation is the researcher's bias. Due to the nature of the study design, the results and findings cannot be generalised as they focus on three individuals specifically, which can in turn mitigate the validity and applicability of these findings to other settings. However, as mentioned before, the aim in dementia care overall should not be to generalise findings and treatments, but instead to focus on providing a better person-centred care to ultimately assess, treat and manage pain appropriately.

In addition, the three case studies included within this chapter reiterate the issues which are still present in dementia specialised care homes, specifically how misinterpretation or lack of time for correct observation of atypical behaviour may lead to inaccurate pain assessment and therefore poor treatment and management of pain. While the solution to the case studies and issues is not straight forward and many complex factors need to be considered, it is also important to continue highlighting and reiterating smaller elements which may hinder quality of life in people living with dementia. Therefore, the “how” and the “why”, which were outlined in Chapter 3 can also be addressed here. The investigation and focus on the “why” observational pain assessment tools are underutilised and “how” the use of the tools can be enhanced has been explored, where the key issues and barriers to a high quality person-centred and holistic care suggested to be high level of workload for care home nurses and GPs, lack of trust between GPs and care home nurses, lack of time due to inappropriate staffing levels at care homes, funding and a need for better communication and education. The identification of these key issues is important as it may not only be useful for future evidence-based change in practice, but also potentially policy change.

7.7 Conclusion

In conclusion, from the three case studies outlined and discussed in this chapter, the issues regarding funding, lack of time and workload for care home nurses as well as potential trust issues between care home nurses and GPs have been highlighted. While here is no singular and simple answer regarding how to address and resolve these challenges, case studies such as this one, are useful in continuing to evidence the problems in care homes. This evidence can potentially be used in the future to inform new policy changes and enhance quality of person-centred holistic care, such as better pain treatment and management through an optimal pain assessment for people living with dementia. One of the key messages of this chapter was that individuals who do express atypical or unexpected behaviours might be expressing pain in an unusual way and therefore, atypical behaviours need to be further investigated to ensure they are understood and the root cause for them is identified, before deciding how to treat and manage the pain.

8 Chapter Eight – Discussion

8.1 Introduction

The final chapter will present a brief overview of the thesis; discuss main findings of all four studies in wider context, outline key strengths and limitations, introduce implications of findings to practice and present the future direction of research. The main aim of this thesis was to examine and compare the psychometric properties, specifically validity and reliability, of observational pain assessment tools for people living with moderate-to-severe dementia in care homes. To achieve this aim, the following four objectives were developed: (a) to conduct a systematic review which further investigated the current state of the observational pain assessment tools, (b) to explore feasibility and use of observational pain assessment tools, specifically the Abbey Pain Scale and the PainChek®, in a UK care home setting, (c) to further validate and evaluate the psychometric properties of PainChek® when compared to Abbey Pain Scale, and (d) to introduce three case studies of individuals who demonstrated atypical pain behaviour and discuss what impact this might have one observational pain assessment.

This PhD thesis addressed the above aim and objectives by systematically introducing the four studies (see Figure 1). Firstly, the literature review (Chapter 2) explored the current knowledge and evidence in the field of pain and dementia, and lead to identifying a gap in the literature. Secondly, the systematic review (Chapter 4) was designed to assess the accuracy and validity of observational pain assessment tools, which have in the literature review. Once the questions from the literature review were further explored and developed for the systematic review, the findings have helped to gain an insight into the strengths and limitations of currently available pain assessment tools used across a range of settings in the world. Additionally, the information from the systematic review helped to structure the design of the quantitative study. Before the quantitative study was designed and conducted, it was important to further explore the views and opinions of nurses and care home staff regarding currently used observational pain assessment tools, specifically the Abbey Pain Scale and the

PainChek®. This was achieved by designing and conducting a qualitative study (Chapter 5), which highlighted some of the concerns and experiences of using the Abbey Pain Scale in care homes.

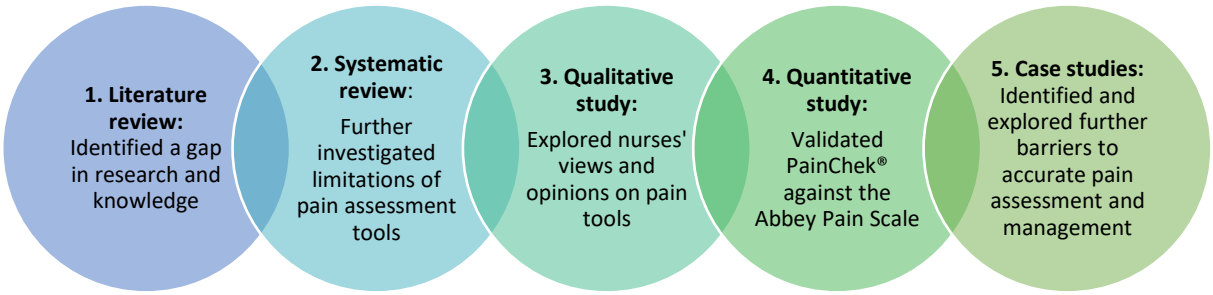

Figure 8.1. The five elements of this PhD thesis

Next, based on all the information gathered within the first three elements of this thesis, the quantitative study (Chapter 6) was designed and developed. In this study, a semi-automated facial expression pain assessment tool called PainChek®, which has previously been validated in Australia (Atee, Hoti, Parsons, et al., 2018) was further validated in the UK. The vision of PainChek® is to offer innovative assessment product which aims to improve quality of life for people in pain and to give a voice to those who cannot verbalise it (PainChek®, 2019). Improving quality of life can be achieved by mitigating some of the limitations of existing pain assessment tools which have been identified and outlined in Chapters 1, 2 and 3.

Further validation, in this case, referred to evaluating psychometric properties of PainChek® in a different country, using a different operating system and recruiting participants from a care home with different dynamics and regimes by an independent researcher. Prior to data collection, a 5-month observational period was completed, where the researcher observed the residents and shadowed the care home staff. This processed enabled familiarity of the care home dynamics, routines and behaviours of residents. During the data collection for the quantitative study, three participants have consistently demonstrated unexpected and atypical pain behaviour. Over the 16

weeks of data collection period, the behaviour of the three participants was observed in more depth. The atypical pain behaviour has been discussed in the case studies chapter (Chapter 7). Including a case study chapter allowed further understanding of some of the potential barriers to accurate and valid observational pain assessment. Furthermore, the detailed exploration of the three case studies offered potential solutions to resolving barriers to accurate and appropriate pain assessment, treatment and management for people living with moderate to advanced dementia.

8.2 Main findings

8.2.1 Systematic review

Many observational pain assessment tools are currently available to identify the presence and severity of pain in people living with dementia. An example of such tools is the Abbey Pain Scale (Abbey et al., 2004), PAINAD (Jordan et al., 2011), CPAT (Cervo et al., 2007), Algoplus® (Rat et al., 2011) and others. The systematic review in Chapter 4, focused on investigating whether the observational pain assessment tools, which have been identified through a comprehensive database search had good psychometric properties and were therefore valid and reliable.

Previously, a systematic review published in 2006 investigated the validity and reliability of pain assessment tools (Zwakhalen et al., 2006). The results of this systematic review stated that most of the observational pain assessment tools, which have been examined, were under development, and have shown only moderate psychometric qualities. However, Zwakhalen et al. (2006) did not conduct a meta-analysis as part of their systematic review, but instead provided a narrative overview and comparison of all studies included. The present systematic review provided an updated version of published articles of observational pain assessment tools between 2007 and 2019 and included a meta-analysis.

The results from the meta-analysis were examined in funnel plots which along with I^2 values revealed highly heterogeneous results for validity and reliability measures of observational pain assessment tools. Due to the high heterogeneity, it is important to interpret and discuss these results with caution. Firstly, it must be noted that some of the heterogeneity presented within the meta-analysis of the systematic review, could be attributed to the wide variety of the population and setting as previously suggested by (Kojima, 2015), rather than simply the validity and reliability scores alone. Secondly, while poor management and treatment of pain in people living with dementia cannot simply be pinpointed to one factor such as the observational pain assessment tools alone, it was important to investigate the impact the heterogeneity may have on pain assessment, treatment and management.

The variability of reported validity and reliability measures across observational pain assessment tools could to an extent explain the ongoing issue with under-detection, underestimation and under-treatment of pain in people with dementia (Peisah et al., 2014). Regardless of heterogeneity, the level of concurent validity, interrater agreement and internal consistency could be higher, espeically for tools which are used to inform the assessor whether pain treatment action needs to be taken. However, as previously stated, these results must be interepeted with caution as there may also be many other complex factors, such as workload, lack of time and staffing within care home or fudning which can contribute towards underutilised and suboptimal use of observational pain assessment tools. In addition, a narrative review approach was taken to investigate further elements of pain assessment. The narrative review explored two elements; the number of pain domains incorporated into observational pain assessment tools and whether the scores from the observational pain assessments were used to increase positive health outcomes. In this case, positive health outcomes focused on factors such as decreasing number of falls or alteration of pain medication to increase accuracy of treatment and management of pain.

Firstly, the narrative review demonstrated that only two observational pain assessment tools; the PACSLAC and the PainChek® have incorporated all six pain domains into the pain assessment. This was a concerning finding, particularly as the AGS (AGS Panel on Persistent Pain in Older Persons, 2002) recommended the use of all six pain

domains for an accurate, valid and reliable observational pain assessment. Secondly, in terms of increasing positive health outcomes, only one study investigated and reported positive health outcomes as a result of regular completion of observational pain assessment. In this case, the number of falls was recorded prior to- and post-implementation of regular use of CPAT (Cervo et al., 2012). The study found that when pain is accurately assessed, treated and managed, the number of falls in a care home is reduced. This potentially suggests that observational pain assessment tools are either not being used often enough or to their full potential, as a more frequent use could lead to reduced number of falls or increase of positive health outcomes. However, it has been acknowledged that the systematic review did not focus on this element of observational pain assessment specifically, and perhaps studies which included more information about this particular element therefore did not meet screening criteria for the systematic review and subsequently were not included. Hence, future research should focus on conducting a systematic review with a meta-analysis to investigate the extent to which frequent use of observational pain assessment tools can aid in decreased number of falls and improved positive health outcomes in care homes, as well as investigating whether the information from the assessments is used adequately.

Lastly, the results from the present systematic review and meta-analysis support those by Zwakhalen et al. (2006), demonstrating that observational pain assessment tools are not only still underdeveloped in terms of not including all six pain domains as outlined in AGS, but also underutilised. However, it is important to take into consideration that heterogeneous results need to be interpreted and carefully, and rather than generalised, the source of the heterogeneity should be examined (Haidich, 2010). It is somewhat concerning that thirteen years later, there now is a better understanding of dementia and pain, more tools to guide care home staff to recognise, observe, treat and manage pain, yet the findings of this systematic review have still shown very similar results to those published in 2006.

8.2.2 Qualitative Study

The second study in this PhD thesis explored the views and opinions of care home staff on current observational pain assessment tools, specifically the Abbey Pain Scale and the ePAT (now known as PainChek®). It was found that only a few studies explored views and opinions or feasibility surrounding newly developed observational pain assessment tools by the target user audience (i.e. care home nurses or formal carers). For example, Practicality of Instruments Survey scores were collected from 18 certified nursing assistants during the development stages of Certified Nursing Assistant Pain Assessment Tool (CPAT) developed and validated by Cervo et al. (2009). The results from this survey have demonstrated acceptable use and perceived feasibility by the participants. Additionally, Zwakhalen, van't Hof, & Hamers (2012) evaluated feasibility by conducting interviews with nursing staff. In the interviews, clarity and usefulness of Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC) was investigated. The analysis of the interviews has demonstrated that PACSLAC was perceived as a tool which is easy to use in care homes, which demonstrated its acceptable feasibility. Investigation of feasibility should be included as part of the validation process for any validation studies in the future, especially studies which develop tools to guide assessors in clinical settings, to ensure that the target user finds the tool user-friendly and easy to use.

Thus, the questions in the semi-structured interviews were designed to explore specific aspects of the observational pain assessment tools; perceived strengths and limitations. Many participants who took part in this study, were already familiar with observational pain assessment tools, whether they used them regularly in practice or have seen them in use by nurses in care homes. Hence, the knowledge and previous experience with the Abbey Pain Scale provided a good understanding of the aspects of the observational tools which the care home staff perceived as either challenges of the tools or highlighted as strengths. This process helped to explore perceived feasibility (i.e. practicality and convenience) of observational pain assessment tools.

Five main themes have been identified Limitations of the Abbey Pain Scale, Strengths of the Abbey Pain Scale, Limitations of the PainChek®, Strengths of the PainChek®

and Critical factors of pain assessment. Within these main themes, participants discussed the usefulness of specific pain domains, such as the facial expression, vocalisation and body language in the Abbey Pain Scale. This was also similar for PainChek®, where participants recognised the usefulness of the enhanced facial expression pain domain feature, which has been fully automated as well as the perceived reduced amount of time it would take to complete the PainChek®. On the contrary, some of the identified limitations of the Abbey Pain Scale included the length of time it requires to observe an individual and complete the scale and that it could be restrictive in terms of the score categories, whereas the PainChek® was perceived as potentially unprofessional due to its use through a mobile device.

While the use of a mobile device can be seen as inappropriate and unprofessional by visitors, mobile technology in clinical settings is now widely used by two-thirds of physicians on regular basis (Mummaneni, Alsalamah, Moussa, & Coustasse, 2015), and the use of mobile devices within this setting has also been accepted by patients (Patel, Green, Shahzad, & Larkin, 2015). Therefore, mobile devices and other technology are likely to replace paper-based systems over the upcoming years.

Additionally, participants spoke about the impact of subjective pain experience on the pain behaviours shown by people with dementia. Participants also stressed the importance of familiarity, in terms of knowing an individual's pain-free behaviour to enhance accuracy of completing an observational pain assessment. Finally, participants discussed how stigma associated with dementia could sometimes influence judgement regarding whether a behaviour portrayed by a person with dementia is linked to pain or a symptom of dementia.

Overall, both observational pain assessment tools which have been discussed as part of the interviews were mostly spoken about positively, demonstrating their usefulness in care homes. In terms of feasibility, participants mentioned that implementation of PainChek® in care homes would be well received, although some training might be required. Thus, the study concluded that the participants spoke about PainChek® positively and were open and enthusiastic about its possible release in the UK.

8.2.3 Validation of PainChek®

The third study of this PhD thesis focused on further validation of a semi-automated observational pain assessment tool – PainChek®. PainChek® has previously been validated and the psychometric properties have been evaluated by Atee, Hoti, & Hughes (2018) and Atee, Hoti, Parsons, & Hughes (2017), however, the validation took place in Perth, Australia using an Android operating system. The present study validated and further evaluated the psychometric properties of PainChek® in the UK using an iOS Apple operating system.

The results from this validation study have further supported the findings by Atee, Hoti & Hughes (2018), as the results from the PainChek® study demonstrated excellent concurrent validity and reliability, therefore indicating that PainChek® is a highly sensitive and suitable pain assessment tool for regular use in care homes.

The novelty element of fully automated facial expression feature mitigated some of the previously reported bias (De Ruddere et al., 2011; Kaseweter et al., 2012) by relying on trained algorithms which can detect facial micro-expression and evaluate presence and severity of pain in the facial expression domain without human input. The results have demonstrated stronger correlations and higher level of validity and reliability when measures were obtained immediately post-movement compared to measures which were obtained at rest. This could be explained by “freezing reaction” while experiencing pain which has been found to be more prevalent in individuals with cognitive impairments (Defrin, Lotan, & Pick, 2006). The freezing reaction or stillness can be misinterpreted for pain-free behaviour as the patient is unlikely to exhibit any other typical pain behaviours such as rocking, whimpering, frowning. However, PainChek® does account for this behaviour, by including a “freezing” item as part of the “movement” pain domain in the assessment. Thus, familiarity of the resident prior to pain assessment is key to differentiating between relaxed and “freezing” state.

Additionally, the history of the resident should also be considered as it may play a role in how individuals are portraying their painful behaviours. For example, previously taught pain acceptance and coping strategies could influence how individual express

their pain, as a study has found that individuals who have been taught acceptance techniques are more likely to have an increased pain tolerance levels (Hayes et al., 1999). Such, it could be argued that if pain acceptance techniques were used in the past, the cognitive process associated with them might still be used unconsciously even once dementia has been developed. However, information about pain acceptance was not collected and therefore it is unclear whether these factors were present, and if so, whether they played any role in the accuracy of pain assessment. That being said, no research has been conducted in this area to determine whether these factors hinder the accuracy of observational pain assessment or how it could be prevented.

It is also interesting to note, that previous research has shown that people who live with chronic pain, often experience cognitive functioning symptoms such as forgetfulness, minor accidents, difficulties completing tasks and difficulties with attention (McCracken & Iverson, 2001). These cognitive functioning symptoms also highly overlap with symptoms of dementia (Alzheimer's Disease International, 2018). Furthermore, a study by Whitlock et al. (2017) found a significant association between chronic pain and subsequent increase of cognitive decline, suggesting a risk of increased memory loss and development of dementia in elders who are living with chronic pain. This, therefore, suggests that presence of chronic pain can increase the progress of cognitive deterioration if the pain is not treated and managed appropriately, which further reiterates the need for an accurate, valid and reliable observational pain assessment tool.

Implementation of PainChek® into daily routine dementia practice could be beneficial. The PainChek® has been validated in Australia and the UK, demonstrating that it is a suitable and appropriate tool to be used to assess the presence and severity of pain in people with moderate-to-severe dementia. Regular use of PainChek® and correct use of the information from the completed PainChek® assessments could lead to reduced more accurate treatment and management pain, decreased number of falls in care homes and overall better quality of end-of-life.

8.2.4 Case Studies

The final study in this PhD thesis introduced three case studies of individuals who demonstrated atypical pain behaviours during data collection for the Validation of PainChek® study. The atypical pain behaviours included smiling when approached regardless of presence and severity of pain, making crying noises until attention was given, and some behaviours were reflected in the pain assessment scores, where resting pain scores were higher than pain scores obtained immediately post-movement. While the scores for both assessors in the Validation of PainChek® study were still similar and represented the same severity of pain, these case studies offered another perspective on presence and severity of pain not only clinically but also from the research perspective.

The aim of the case study chapter was to highlight the importance of investigating individual differences in people living with dementia, and the need to consider those who do demonstrate their pain behaviours atypically. Although case studies have been criticised for researcher bias and general subjectivity, they can offer further insight into anomalies in existing theoretical and practical propositions (Levy, 2008). In this case, three anomalies, i.e. individuals who did not fit in with the rest due to showing atypical pain behaviours, were selected for further observation.

In two of the cases, it was noted that better interprofessional education and communication could enhance more accurate and holistic care of not only people who show atypical pain behaviour but people with dementia overall. Interprofessional education is an intervention where health professionals of two or more health or social care professionals learn to collaborate together for the sole purpose of improving health and wellbeing of clients (Reeves, Perrier, Goldman, Freeth, & Zwarenstein, 2013). In addition, Interprofessional education aims to train health care professionals to work together as a ream, to address needs of individuals and enhance person-centred and holistic care. Therefore, the implementation of interprofessional education would be particularly of importance in cases where the communication between allied health professionals breaks down.

In addition, case studies such as this one may be used for educational purposes of undergraduate and nursing students, to highlight the individual differences and different experience of pain in people with dementia. This information might prompt lateral thinking when the imminent workforce is faced with a similar situation. Lastly, while generalisability of studies to cohorts or populations can be useful, sometimes acknowledging and being aware of how individual differences can affect results is important. Hence, each patient should be considered as an individual rather than generalised as part of a cohort, and a holistic, person-centred approach should be considered in all people living with dementia, especially in cases when pain might be portrayed differently. This might lead to a more accurate and reliable pain assessment and thus pain treatment and management in the future.

8.3 Methodological reflections

The strengths and limitations of individual research studies have been discussed throughout the chapters. The following subsections summarise the previously outlined strengths and limitations and evaluate them in terms of the overall PhD thesis and its original contribution towards current knowledge.

8.3.1 Strengths

One of the strengths of the PhD thesis and the PainChek® study specifically was validating a tool which mitigates some of the human error and bias in observational pain assessment. Mitigating and eventually eliminating human error and bias may lead to more accurate and reliable pain assessment, which may lead to more appropriate pain treatment and management.

Additional strengths of this PhD thesis include a robust and thorough methodology, which minimised bias across the studies. In the validation of PainChek® study, bias

was reduced by blinding the two raters to each other's scores. The rater who completed the PainChek® assessments (i.e. the researcher of this thesis) was also blinded to whether the participants took any pain management medication to prevent learning bias. In addition, pain was assessed during various days and times in the week, including before or after breakfast, during transfer from bed to a wheelchair, during rest time, pre- or post-activity and during visitation period. Assessing pain during a range of times and days reflected real-life clinical settings and conditions which strengthened the pragmatic aspect of this study.

The systematic review has taken several measures to ensure a thorough systematic process. The quality assurance and risk of bias assessment checklists were completed with an additional researcher to prevent researcher bias and ensure a high quality of the article. The qualitative study adopted an inductive data-driven approach where data were coded prior to application of theoretical underpinning to reduce bias. Lastly, while it is acknowledged that the case studies could have been biased as they are outlined in Chapter 7, the individuals included in this chapter were representative of those who do not fit in with the norm and show atypical behaviours of pain.

The findings in this PhD thesis also outline some unique and original contribution to the current body of research. First of all, although dementia has become a public health priority in 2012 (World Health Organisation and Alzheimer's Disease International, 2012), the updated systematic review demonstrates many similar findings to those conducted 12 years ago by Zwakhalen et al. (2006). The studies in this PhD thesis could contribute towards a global aim to continue conducting research in dementia, and continue developing and implementing interventions which can advance not only an understanding of a more accurate pain assessment, treatment and management, but also ways to increase quality of life at end-of-life dementia stage in individuals. Thus, the research presented in this PhD thesis provides unique and original findings which contribute to and build upon already existing research.

8.3.2 Limitations

A few limitations of this PhD thesis have been acknowledged. First, the validation of PainChek® study only had a small sample size and small cultural and ethnical diversity; however, the ethnicity (i.e. mostly white British participants) of the participants recruited in this study, represented the general ethnicity statistics in the UK. For example, In England and Wales 86% of the population is white, followed by 7.5% Asian, 3.3% Black, 2.2% mixed or multiple ethnic groups and 1% other ethnic groups (Office for National Statistics, 2018). Additionally, regardless of the smaller sample size (N = 22), correlational saturation was reached with the number of paired pain assessments obtained (N = 302).

Another limitation of this PhD is the measures that were utilised to test for feasibility in the qualitative study. While the exploration of views and opinions has been useful to understand the key perceived strengths and limitations of the Abbey Pain Scale and the PainChek®, different measures could have been included in addition to the qualitative interviews, to provide a better understanding of perceived feasibility. For example, the Practicality of Instruments Survey (Cervo et al., 2009) or the User Engagement Scale (O'Brien, Cairns, & Hall, 2018) could have been incorporated. The User Engagement Scale, in particular, could be a useful tool to measure engagement as well as feasibility, as it focuses specifically on technological human-computer interactions, and measures aesthetic appeal, focused attention, novelty, perceived usability, felt involvement and endurability. Future validation and implementation of PainChek® research should also include established feasibility measures such as the User Engagement Scale, to further investigate feasibility.

In addition, during the validation process, only one nurse who completed the Abbey Pain Scale assessments were recruited. As such, it could be argued that the validation process could have been somewhat biased. However, measures such as blinding the assessors to results from each other's assessments were taken, to enhance strength of the study and report findings that are representative of the reliability and validity of PainChek®. Future validation and evaluation of psychometric properties could be

enhanced by not only recruiting several nurses but also validating PainChek® against observational pain assessment tools other than the Abbey Pain Scale.

8.4 Unique findings

The findings of this thesis indicated that there were some unique elements which considerably affected the data collection process in the UK compared to the first validation of PainChek® study in Australia (Atee et al., 2017a). One of these findings has been discussed in Chapter 6, where it was found that while information such as change in sleeping pattern or appetite was recorded, due to the dynamics and responsibilities of roles within the care homes not all care home staff had access to some of the elements of the assessment which was vital when completing the PainChek® pain assessment. This included information about the items in the activity pain domain (e.g. resisting care, prolonged resting, altered sleep or routine). This could be considered as a difference between the UK and Australia and thus should be considered when PainChek® is implemented for UK care homes. Fortunately, the care homes in the UK keep a thorough and up-to-date track of any changes in the patters outlined in the activity pain domain, therefore if care home staff are unable to complete this section they could retrace this information through their internal care systems.

It was also worthy to note that regardless of the variation of care home dynamics between the UK and Australia, the PainChek® has demonstrated to be a highly accurate observational pain assessment tool in terms of validity and reliability despite the cultural and dynamic differences. For example, in the UK, the pain assessments were completed in communal spaces rather than in isolated rooms. This reflected the procedure which would have been undertaken in a real-life care home setting in the UK. At times, the communal areas were loud, with films being shown on the TV or activities taking place. It could be thought that the surrounding noise and movement could have distracted the participant from their pain; however previous research has demonstrated that distraction failed to reduce the physiological or behavioural response to pain (McCaul, Monson, & Maki, 1992). In addition, as mentioned before,

taking this approach to data collection replicated the real-life situation of how care home staff would have assessed individuals if they had started to express pain behaviours.

Lastly, it is also important to highlight the value of digitalising routine procedures such as pain assessment. Moving towards a digitalised care could have positive effects on documentation and workflow, which can lead to a quicker and more reliable way to save, store and share important clinical notes within settings, especially as lack of time, high levels of workload and staffing issues have been identified throughout the thesis. Implementing an electronic device which can be linked or synchronised to local patient databases automatically and upon completion of pain assessment, would decrease paperwork burden which care home nurses and staff are faced with on daily basis.

PainChek® has an open Application Programming Interface (API) which allows easy implementation with systems and software which are already in use in care homes. Open API also allows a simple transfer of information between systems and devices, allowing instant access to information such as pain assessment, management or administration of analgesic for patients. In addition, PainChek® allows the user not only to record presence and severity of pain, but also medical information, analgesic use and other non-medication pain interventions. This helps all staff with access to PainChek® to instantly access this information and make an informed person-centred care decision regarding pain treatment or management. Recording and instantly accessing this information can help detect pain at early stages and therefore not only treat it more appropriately, but also prevent potential falls or unnecessary administration of antipsychotics or other inappropriate medication.

Another unique element was found in the qualitative study. In terms of feasibility, the care home staff who have viewed the PainChek® video have demonstrated that they could see the implementation of an electronic pain assessment tools within a dementia specialised care home setting. Exploring and understanding the perceived strengths and limitations of the observational pain assessment tools which are already used within a care home setting as well as one which is hoped to be implemented in the future, allows the researchers and developers of PainChek® to consider making further

improvements to the tool. In addition to this, the application of the key theme and sub-themes identified within the qualitative study to the COM-B approach indicated how perceived capability, opportunity and motivation can influence or change behaviour. Some interview participants highlighted the time consuming and paperwork element of their current observational pain assessment tool to be a limitation and a barrier to frequent use of the tools. The lack of time and paperwork burden has also been highlighted within other chapters and can explain why observational pain assessment tools are underutilised.

In terms of the systematic review with a meta-analysis, the somewhat concerning yet unique findings demonstrated that many of the same barriers and issues which have been highlighted in studies from 2007 are still present this day. For example, the suboptimal use of observational pain assessment tools and the heterogeneity of accuracy and reliability together could indicate that more rigorous validation processes are needed. However, as mentioned before, pain assessment, treatment and management are complex and other factors need to be considered in order to understand and tackle the wider issue of pain in dementia.

The three case studies added an evidence-based individualistic approach which highlighted how atypical pain behaviour can skew or hinder pain management and treatment in people living with dementia. The case studies aimed at draw attention to individuals who were expressing pain in a different manner to that which is usually reported. The behaviours which the three participants demonstrated; smiling when approached even when experiencing pain, making crying noises when not experiencing pain and showing higher pain severity when resting compared to post-movement. These behaviours are not found within he six pain domains as outlined by AGS (2002) and therefore could be misinterpreted or overlooked when assessing presence and severity of pain in people living with dementia. Within the case study chapter, the author has indicated how pain assessment and management can be improved to enhance quality of life in people with dementia. The suggestions for improvement included considering the implementation of better education and knowledge to enhance trust between care home staff and GPs, increasing funding to ensure appropriate number of staff are available for a person-centred and holistic care and findings ways to decrease workload and paperwork burden, such as implementing

electronic rather than paper-based devices, such as PainChek®, which allows instant access to history of residents and has the potential to store pain assessments directly to local patient systems.

Lastly, while all these findings are unique and can contribute towards future research-based changes in policies and regulations, it is also important to note that the link between underutilisation of observational pain assessment tools and poor pain management and treatment is only a very small aspect of pain in dementia. Pain treatment is complex and cannot simply be fixed by increasing the frequency of use of observational pain assessment tools. However, ensuring correct and accurate use of observational pain assessment tools through an evidence-based implementation, training and education can be the first step towards better quality of life in people living with moderate-to-severe dementia. In addition to this, conducting research studies such as those presented within this thesis, continue to highlight existing issues but also uncover new issues which need more investigation.

8.5 Future direction of research

Future directions of research have been discussed throughout this chapter. To summarise, future research should investigate the feasibility of any observational pain assessment tool as part of its validation process to ensure correct use and enhance frequency of use of the tool. Research should also focus on examining how adequate use of observational pain assessment tools can be improved so that the information from the pain assessments is used appropriately and acts as a guide for a better person-centred and holistic dementia-care in terms of recognising, assessing, treating and managing pain. Additionally, future research should focus on implementing PainChek® into care homes longitudinally and investigate whether appropriate and frequent use increases positive health outcomes.

8.6 Conclusion

In this thesis, psychometric properties of observational pain assessment tools for people living with moderate-to-severe dementia has been examined. Initially, a literature review revealed issues with pain in dementia in terms of ongoing under-recognition, underestimation and under-treatment of pain. Then, the systematic review built upon the initial findings by further investigating the reasons behind poor pain treatment and management in people living with dementia using observational pain assessment tools. The findings have demonstrated inconsistency in reported validity and reliability measures across a number of observational pain assessment tools, which was reflected by heterogeneous meta-analysis results. The findings from the meta-analysis suggested that regardless of recommendations set out by the American Geriatrics Society panel on persistent pain in older people, only minority of currently available tools follow the set recommendations. Next, feasibility of PainChek® was explored in a qualitative study which investigated views and opinions of care home staff.

The most common limitations which were spoken about were time consumption and restriction of pain domains for the Abbey Pain Scale, and the use of phone in a professional environment and facial reaction of a resident to a phone device for PainChek Strengths included facial expression domain for both tools and decreased time consumption for PainChek®. Following the qualitative exploration study, PainChek® was validated and evaluated for psychometric properties in the UK. The results have indicated that PainChek® would be an appropriate pain assessment tool to be implemented in UK care homes. Lastly, individual case studies were highlighted and their importance in pain assessment was highlighted. Participants which showed atypical pain behaviours would have often been deemed as outliers and excluded from analysis. In this thesis, the atypical behaviours were investigated in-depth, and suggestions regarding how atypical behaviours should be approached to achieve an appropriate and holistic dementia-care were made. Mostly, the recommendation indicated that better collaboration and communication between professionals was needed, which could be resolved with implementation of interprofessional education into undergraduate and nursing associate programmes.

This thesis had the following aim: to examine and compare the psychometric properties of observational pain assessment tools for people living with moderate-to-severe dementia in care homes, and the following four objectives; to conduct a systematic review which further investigates the current validity and reliability of observational pain assessment tools, to investigate views and opinions of care home staff about observational pain assessment tools, to further validate and evaluate the psychometric properties of PainChek® when compared to Abbey Pain Scale in a UK setting, and to introduce three case studies of individuals who demonstrated atypical pain behaviour and discuss what impact this might have one observational pain assessment. The four objectives in this thesis were met and therefore the overall aim was achieved. This thesis has shown that assessment, treatment and management of pain in dementia is still an issue, but the right steps are being taken to mitigate factors which hinder accurate and adequate pain assessments.

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Appendices

Appendix 4.1: PROSPER registration confirmation for systematic review

NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Pain in people with dementia: a systematic review of the effectiveness of observational/behavioural pain assessment tools
Ivana Babicova, Ainslea Cross, Dawn Forman, Kreshnik Hoti, David Sheffield, Ann Kirkman

Citation
Ivana Babicova, Ainslea Cross, Dawn Forman, Kreshnik Hoti, David Sheffield, Ann Kirkman. Pain in people with dementia: a systematic review of the effectiveness of observational/behavioural pain assessment tools. PROSPERO 2017 CRD42017053598 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42017053598

Review question
When compared to one another, how effective are observational/behavioural pain assessment tools for people with dementia/a lack of verbal skills in the UK (in terms of accuracy and inter-rater reliability)?
Do observational pain assessment tools result in accurate treatment of pain (e.g. recognised pain is correctly treated with analgesics)?
Does correctly recognised and treated pain in people with dementia/a lack of verbal skills result in a positive health outcome?
What methods do the pain assessment tools use to obtain data about pain (e.g. domains such as psychological, physiological, physical, verbal, type of scale, etc.)?

Searches
The review will include searches from the following electronic databases:
PsycINFO, Web of Science, ScienceDirect, University of Derby Library Plus.
The search will be restricted to articles published between 2007 and 2017 (i.e. the past ten years) to ensure that the material used is current.
The search will be restricted to:
Studies published in the English language, with full texts available.

Types of study to be included
Inclusion criteria: peer reviewed published studies which describe an assessment intervention/tool for dementia or subgroups of dementia (e.g. Alzheimer's) or for individuals with impaired or limited verbal communication skills. Articles must have been published in the English language, and randomised controlled trials, cohort studies, observational studies and experimental studies will be eligible for inclusion, if they have investigated observational/behavioural pain assessment tools. Only pain assessment tools which have been designed specifically for people with dementia or a lack of verbal skills will be included. Only articles with available full texts will be included.
Exclusion criteria: secondary analysis papers (reviews and meta-analyses), and case study reports.

Condition or domain being studied
Pain in people with advanced dementia or nonverbal elderly.

Participants/population
Human participants, specifically older adults and elderly people.
Inclusion criteria: older adults and elderly with dementia (any sub-type - as diagnosed using any recognised diagnostic criteria) or older adults and elderly who have no/lack of verbal skills. Exclusion criteria: adults (under the age of 50).

Intervention(s), exposure(s)
The reviewed pain assessment tools will be any observational/behavioural pain assessment tool designed for people with no or impaired of verbal skills (e.g. Abbey Pain Scale, Pain Assessment in Advanced Dementia (PAINAD), Non-Communicative Patient's Pain Assessment Instrument (NOPPAIN) and more). Criteria for impaired verbal skills or no verbal skills will be based on participants possession of formal certificate for impaired speech or carers or frontline staff's (nurse, GP) judgement.

Comparator(s)/control

Other interventions, randomised control trials.

Context
Only studies from hospital, residential care homes and GP settings will be included.

Main outcome(s)
Health outcomes and behaviours indicative of decreased pain.

Timing and effect measures

All outcomes will be measured either through self-report, observation and reports of staff/researcher or change of behaviour (e.g. analgesic medication adjusted based on assessment tool pain severity score and psycho-physiological measures of pain detection).
Health outcomes - decreased pain - as a result of correctly detected, assessed and consequently treated pain using observational/behavioural pain assessment tools will include a decrease in pain indicative behaviours. These pain indicative behaviours are:
- Facial expressions (e.g. frown, frightened face, grimacing, wrinkled forehead, closed or tightened eyes or rapid blinking),
- Verbalisation or vocalisation (e.g. sighing, moaning, groaning, grunting, calling out, noisy/loud breathing, asking for help),
- Body movements: (e.g. fidgeting, pacing, tense body posture, gait/mobility changes, rocking, pacing, restricted movement),
- Changes in interpersonal interactions (e.g. aggressive behaviour, care resistance, disruptive behaviour, withdrawn behaviour and verbal abuse, decreased social interaction),
- Changes in activity patterns or routines (e.g. refusing food, appetite changes, changes in rest and sleep pattern, sudden cessation of common routines),
- Mental status changes (e.g. crying, increased confusion and irritability, distress).
Any indication of decrease in behaviour outlined above will be classed as decreased pain as a result of correct detection, assessment and treatment of pain.

Additional outcome(s)
Measures such as increased psycho-social well-being and increased quality of life.

Timing and effect measures

Quality of Life measures for dementia and individuals with lack of verbal skills such as Quality of Life in Late-Stage Dementia (QUALID), Health-Related Quality of Life in People with Dementia (DEMQOL), and any other scales used to measure quality of life for people with dementia or people with lack of verbal skills will be used to evaluate and review change in quality of life in participants.
Any other measures and scales used to measure improvement in quality of life (including psychological well-being, improvement in health related condition) which the reviewer might come across during initial screening of articles will be recorded and reported in the review.

Data extraction (selection and coding)
The reviewer (IB) will complete two separate data extraction sheets for each selected study (PRISMA and CASP). Each study will then be assessed for bias against Cochrane tool for bias. The reviewer will extract and record all the data collected from individual studies into an Excel spreadsheet, and data extraction sheets.
The studies will be initially screened for the following:
Whether they are written in the English language;
Whether there are full text versions available;
Whether they fulfil the participant exclusion and inclusion criteria;
Whether the type of study is eligible for inclusion (the exclusion and inclusion criteria will be applied). Following the initial screening, the studies will then be screened by their titles and abstracts, and those which potentially meet the inclusion criteria will be independently assessed based on their retrieved full texts.

Risk of bias (quality) assessment
The reviewer will complete Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Critical Appraisal Skills Programme (CASP) forms, for each selected study. For observational and experimental studies, Risk of Bias in Non-Randomised Studies (Robins-I) tool will be used, Cochrane's risk

of bias tool will be used. All tools will be used for initial screening (during the exclusion/inclusion of articles phase) and prior to in depth analysis and write up phase.

Strategy for data synthesis
The accuracy and validity of behavioural pain assessment tools will be analysed according to outcomes and results from articles included in the review. Narrative synthesis (NS) of all selected studies will be conducted, which will include a table of participant demographic and other information, intervention type information, settings and outcomes.

Analysis of subgroups or subsets
If necessary data are available, analysis of subgroup or subsets will be provided. These subgroups will consist of condition (1. individuals with dementia diagnosis, 2. non-verbal individuals without the diagnosis of dementia), and setting (1. hospital, 2. GP, 3. care home/residential home, 4. other). Further subgroups might occur once the initial screening of articles has been completed.

Contact details for further information
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Organisational affiliation of the review
University of Derby
www.derby.ac.uk

Review team members and their organisational affiliations
Miss Ivana Babicova. University of Derby
Dr Ainslea Cross. University of Derby
Professor Dawn Forman. University of Derby
Dr Kreshnik Hoti. University of Pristina
Professor David Sheffield. University of Derby
Miss Ann Kirkman. University of Derby

Type and method of review
Systematic review

Anticipated or actual start date
24 April 2017

Anticipated completion date
24 April 2018

Funding sources/sponsors
University of Derby (as part of the researchers Fees Only Doctoral Bursary).

Conflicts of interest
One of the lead reviewer's supervisor (KH) is currently involved in development of a new commercial pain assessment tool for people with dementia. The other authors declare no known conflict of interest.

Yes
Language
English

Country
England

Stage of review
Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Dementia; Humans; Pain; Pain Measurement

Date of registration in PROSPERO
19 April 2017

Date of publication of this version
06 September 2017

Revision note for this version
Minor changes only: updated systematic review progress and added a member to the review team.

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	No
Risk of bias (quality) assessment	Yes	No
Data analysis	No	No

Revision note
Minor changes only: updated systematic review progress and added a member to the review team.

Versions
19 April 2017
21 June 2017
06 September 2017

Appendix 5.1: Ethical approval for qualitative study from College of Health and Social Care, University of Derby

Approved

13/09/2017

Name: Ivana Babicova

Dear Ivana

Topic: An investigation into feasibility, views and opinions of PainChek® and other pain assessment tools for people with dementia: a thematic analysis.

Thank you for submitting your application to the Health and Social Care Research Ethics Committee.

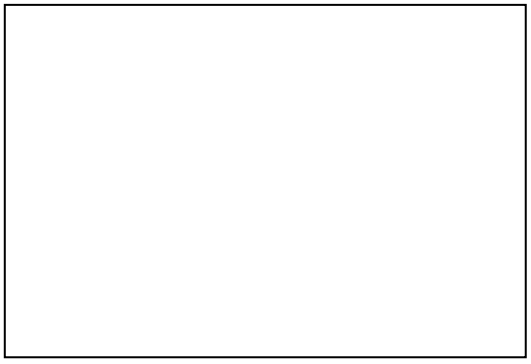
Your study has been approved by chairs action

If any change to the study described in the application or to the supporting documentation is necessary you are required to make a resubmission to the Health and Social Care Research Ethics Committee.

We will also require an annual review of the progress of the study and notification of completion of the study for our records.

All the best with the study

Yours sincerely,



Chair, Health and Social Care Research Ethics Committee

Appendix 5.2: Participant recruitment and study documents (Invitation to participate, Participant Information Sheet, Consent Form and Debrief)

INVITATION TO PARTICIPATE

Dear Sir or Madam,

I'd like to invite you to take part in my doctoral research project titled: **An investigation into feasibility, views and opinions of PainChek® and other observational pain assessment tools for people with dementia: a thematic analysis**. I am currently a PhD Research student at University of Derby, and I am in the process of collecting data for my doctoral thesis.

The purpose of this study is to investigate views and opinions on current pain assessment methods used in UK care homes and hospital settings. The study is designed to interview variety of individuals who have either experienced pain assessment methods themselves, know of someone who is regularly assessed for pain using tools designed for non-verbal individuals (such as people living with advanced dementia), and also people who have never heard of any pain assessment tools.

Participation in this research is completely voluntary. Whether you decide to accept and take part in the research, or decline altogether your decision will not be questioned. There are no known risks to participation beyond those encountered in everyday life. Your response will remain confidential and anonymous. Data from this research will be kept in an encrypted, password protected external storage, and reported only as collective combined total. The data collection, storage, analysis and reporting will comply with the Data Protection Act (1998).

This study has been approved by University of Derby, College of Health & Social Care Research Ethics Committee.

If you agree to participate in this project, please let the researcher know via email or telephone given below.

If you have any questions about this project, feel free to contact the researcher – **Ivana Babicova** via email **i.babicova@derby.ac.uk** or **TEL: 01332 592 549**

Thank you for your assistance in this important endeavour.

Sincerely yours,

Ivana Babicova

PARTICIPANT INFORMATION SHEET

About researcher: My name is Ivana Babicova, and I am currently a PhD Research student at University of Derby. I am interested in improving quality of life in people living with dementia, through investigating current and future pain assessment methods. If, after reading this form, you have any further questions please do not hesitate to contact me at: **i.babicova@derby.ac.uk or TEL: 01332 592 549**

About this information sheet: The Participant Information Sheet is designed to help you decide whether you'd like to take part in this study. It sets out the purpose of the study, what your participation would involve, what the benefits and risks to you might be, what happens after the study ends, and any other information including contact details of the researcher.

If you agree to take part in this study, you will be asked to read and sign a Consent Form. You will also be given a copy of both the Participant Information Sheet and a Debrief form for you to keep.

Please make sure you have read and understood this sheet, before signing the consent form. You do not have to take part in this study if you do not wish to. If you decide to take part in this study, but later decide you no longer wish to continue, you can withdraw your data from the study without giving a reason (see **about withdrawal** section).

About the study: The purpose of this study is to investigate views and opinions on current pain assessment methods used in UK care homes and hospital settings. The study is designed to interview variety of individuals who have either experienced pain assessment methods themselves, know of someone who is regularly assessed for pain using tools designed for non-verbal individuals (such as people living with advanced dementia), and also people who have never heard of any pain assessment tools.

About participation: If you decide to take part in this study, you will be interviewed by the researcher, to help gain an in-depth insight into current pain assessment interventions for non-verbal people. Prior to the interviews, you will be asked to fill out a quick 24-item survey which has been designed to assess beliefs and knowledge surrounding pain tools used for non-verbal elderly. Following the completion of this survey, the research interviews will commence. The interviews will focus on two pain assessment tools: one which is already widely used in UK care homes, hospitals and/or other settings, and another which is a newly developed tool provided by ***PainChek***®.

Please note that you do not need to have any knowledge about either of these tools (or any pain assessment tool). You will be introduced to both tools by the researcher.

Please allow up to ***45 minutes*** for this study, although it is unlikely that the interviews will take this long. The study will either take place at University of Derby, the care home which you're currently based at or an alternative agreed public place (**date, time and place can be arranged with the researcher via email**). As part of the study, the researcher will ask for your consent to allow audio recordings of the interview, to enable creating transcripts and analysis of the interview. You will be asked to create a pseudo name for the interview. Only your pseudo name will be used in the interview transcriptions to ensure anonymity and confidentiality. The original audio recording will be stored on an encrypted USB and transcribed. To comply with University of Derby Research Ethics Policy and Code of Practice (June 2013) and as a part of the Records Retention Policy (March 2014), the audio recordings have to be securely stored and kept for a minimum of 6 years before the researcher is able to destroy them.

About withdrawal: If you no longer wish to continue taking part of the study (either during the interview or after the interviews) you have the right to withdraw your data from the study without having to provide a reason. The researcher will not question or jeopardise your decision. If you do wish to withdraw your data from the study, please email the researcher with your unique code and pseudo name. After the researcher receives this information, all data collected from you will be destroyed, and will no longer be used in the investigation.

If you do wish to withdraw your data, please let the researcher know, to ensure your data is withdrawn from the data set prior to analysis and write up of investigation.

Researchers email address: **i.babicova@derby.ac.uk** or **TEL: 01332 592 549**

About confidentiality and security: The data will be stored securely in a password protected folder on a computer to which only the researcher has access to. The consent forms with your name and signature will be stored separately to any other information or data. You will be asked to create a unique code (see more in **About unique code** section), which will be used on all data sheets, to ensure anonymity and confidentiality. Only the researcher and their supervisors will have access to collected data.

About unique code: If you decide to take part in the study, you will be asked to create a unique code (on the bottom of this form, and again on Consent Form). The researcher will label all data collected from you (including gender, age and ethnicity background) with your unique code. The unique code will consist of last three letters of your surname, two digits of your birth month, and last three digits of your phone number. If you do not have a phone number, the last three digits of the unique code can be made up. This is to ensure confidentiality, anonymity and to prevent tracking of participants.

For example: If a participant named John Smith born on 24th February 1987 with a phone number 07712345678 was to create a unique code, it would look like this:

ITH02678

About transcript anonymity: Additionally, to creating a unique code, you will also be asked to create a pseudo name, which will be used in the transcripts, and referred to in write up stage. This is to ensure your anonymity and security.

Lastly, if you have any questions, concerns or complaints about the study at any stage, please do not hesitate to contact the researcher.

Ivana Babicova (PhD Research Student)
College of Education
University of Derby
i.babicova@derby.ac.uk

The researchers' supervisors are:

Dr. Ainslea Cross
Academic Lead for Health Psychology
University of Derby Online Learning

Prof. Dawn Forman
Director, Interactive Leadership and Management Development
Visiting Professor, University of Derby and Chichester University
Adjunct Professor Curtin University and Auckland University of Technology

Asst. Prof. Kreshnik Hoti
Vice Dean for Academic Affairs
Faculty of Medicine
University of Prishtina

Thank you for taking your time to read through this form.

If you wish to take part in the study, please make a note of your unique code here:

_____

CONSENT FORM

Please read the following statements carefully:

I, the undersigned, confirm that (tick box as appropriate)

☐ I have read and understood the information about the study, as provided in the Participation Information Sheet (Version 2.3, August 2017).

☐ I give my consent for audio recordings of the interview.

☐ I understand that this study consists of semi-structured interviews and a 24-item survey.

☐ I have been given the opportunity to ask questions about the study and my participation.

☐ I voluntarily agree to participate in the study.

☐ I understand I can withdraw for **up to 6 weeks** after I have taken part in the study, without giving any reasons.

☐ I understand that withdrawing from the study will not result in any penalisation or any questioning regarding withdrawal.

☐ I agree that the procedures regarding confidentiality have been clearly explained to me (e.g. the use of unique participant code) and I understand that my data will be stored securely.

☐ I consent to give the researcher information regarding my age, gender and ethnicity background for demographic analysis purposes.

☐ I understand that only the researcher and their supervisors will have access to this data.

☐ I, along with the researcher, agree to sign and date this consent form.

Participant:

_____	_____	_____
Name of Participant	Signature	Date

Researcher:

_____	_____	_____
Name of Researcher	Signature	Date

DEBRIEF

Thank you for taking part in the study.

The study was aimed to explore your views and opinions on current pain assessment tools (such as Abbey Pain Scale) used in care homes for people who either have limited or no verbal ability.

Currently, the pain assessment tools (including Abbey Pain Scale) used worldwide are very effective at detecting and assessing for pain in people who struggle to communicate or cannot communicate at all, such as young children, people with learning disabilities and people with advanced dementia. However, previous research has suggested that there are factors which can affect the accuracy of these pain assessment scores, and can consequently result in mistreatment of pain. These factors include unconscious or conscious bias, lack of training, lack of time in busy environments to assess pain and many others.

Firstly, you have been asked to answer 24-question survey called: The Pain in Older Adults Knowledge Survey (POAKS), which will enable the researcher to understand some of the answers you may have given in the interviews.

Additionally, the research project divided into two phases – two semi-structured interviews. The first phase was designed to investigate your knowledge, views, opinions and experience of currently used pain assessment tools. The second phase was designed to explore your views and opinions of the newly introduced ePAT (Electronic Pain Assessment Technologies, Pty Ltd) pain assessment tool.

I would like to thank you for participating in this research project, and also remind you that if for any reason you no longer wish to include your data in the study, you have the right to withdraw at any time **for up to 6 weeks** after taking part in the study. To do so, please contact the researcher using the email address below, quoting your unique participant code and pseudo name.

Please make a note of your Unique Participant Code and Pseudo Name below:

If you have any further questions, please do not hesitate to contact the researcher or supervisors:

E-mail address (researcher): i.babicova@derby.ac.uk

E-mail addresses (supervisors):
Dr. Ainslea Cross: a.cross@derby.ac.uk
Prof. Dawn Forman: dawn@ilmd.biz

Thank you again for your cooperation.

SEMI-STRUCTURED INTERVIEW QUESTIONS 1 (General)

Introduction: Hello, my name is Ivana Babicova, I am a PhD Research student at University of Derby, and I am currently exploring views and opinions of current pain assessment methods for non-verbal people in the UK.

1) **Are you aware of any pain assessment tools used for people with lack of verbal skills in the UK? - If yes, what tools? (name? description?)**
   -If no, skip to question 2b

2) **2a) Can you tell me a bit about what you know about pain assessment tools for people who have limited verbal skills?**

   OR (if question 1 is answered with "no")

   2b) Can you tell me a bit about what you think of when someone says "pain assessment tool for people with lack of verbal skills"

Probe: let the interviewee explain their idea of pain assessment tools
Explain to interviewee pain assessment tools used (if the participant has no idea, show the participant the Abbey Pain Scale)

3) **Could you describe what a good pain assessment tool would look like to you.**

   Prompt: If participant is aware of tools: Personal knowledge and/or views and opinions. Relate to own experience/ experience of seeing someone being assessed/ assessing someone personally. **Prompt:** Strengths?

   Explain to the interviewee how exactly the pain assessment tools work – scoring basis in different domains such as: the face, behaviour, vocal indicators….
   For example, and observer will give a score of 0-3 (0 = pain not present, 3 = severe pain present) based on observing an individual in different domains.

4) **What do you think the challenges might be in pain assessment in individuals with lack of verbal skills?**

   Probe: Concerns? + elaboration
   Prompt: Try putting yourself in shoes of a person who is observing a non-verbal individual to see if they are experiencing pain. How do you think you'd do, if you had a tool to follow?

5) **And how do you think these challenges could be improved?**

   Prompt: If you were a person who could not communicate, how would you tell others that you are in pain? How could others better recognise pain?

Thank you for your time. Do you have any further questions regarding the interview or the study you'd like to ask me?

SEMI-STRUCTURED INTERVIEW QUESTIONS 2 (ePAT)

Introduction: Hello, thank you for attending the second session of the interviews. Just as a reminder, my name is Ivana Babicova, I am a PhD Research student at University of Derby, and I am currently exploring feasibility and acceptability of ePAT provided by Electronic Pain Assessment Technologies (ePAT) Pty Ltd.

6) **Have you heard of ePAT before?**

Likely answer – no.
Some

If NO – researcher shows the participant the ePAT website including a video which explains how it works.

7) **What do you think about ePAT as a tool?**

Like the idea of it/ liked how it worked. Dislike it? Why?

Probe: User friendly? Fast? Accurate? Can they imagine themselves using it in the future? How? Why? + Elaboration
Prompt: Thoughts on technology detecting pain

8) **Is ePAT something you can imagine yourself/care homes and hospitals (depends on type of interviewee) use in near future and why?**

Yes? No?
Why? Does the interviewee think it needs some improvements?
Probe: Elaboration of answer

How do you think ePAT compares to current pain assessment tool (Abbey Pain Scale or other)
Probe: Strengths and limitations
Prompt: Comparison

Thank you for your time. Do you have any further questions regarding the interview or the study you'd like to ask me?

Appendix 5.3: Approval for data collection from a care home

ORCHARD™
Care Homes
www.orchardcarehomes.com

Ref: SW/LL/Z/COMP/ePat

5th January 2017

[redacted]
Director of Quality & Clinical Governance
Orchard Care Homes
Harrogate
North Yorkshire
HG2 8RE

Dear Ivana

I can confirm that I discussed you proposal for the ePat project with our ethics committee in November, and confirm that we have agreed that you can undertake the research within 2 of our homes

I trust this is the information you require, however if there is further clarity needed then please contact me further

Kind regards

[redacted]

Director of Quality and Clinical Governance

The Hamlet, Hornbeam Park, Harrogate HG2 8RE Tel: 01423 859859 Fax: 01423 859860
www.orchardcarehomes.com

INVESTOR IN PEOPLE

Appendix 6.1: Ethical approval for Validation of PainChek® study from the College of Health and Social Care, University of Derby

Date: 12/09/2018

Name: Ivana Babicova

Dear Ivana

Topic: A Research into the Validity, Accuracy and Feasibility of PainChek - an electronic pain assessment tool for Individuals with Dementia in UK Care Homes.

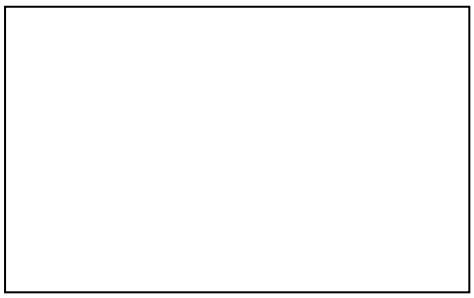
Thank you for submitting your application to the College of Health and Social Care Research Ethics Committee.

Your study has been approved by the Committee and you are now able to proceed.

Once the study commences if any changes to the study described in the application or to the supporting documentation are necessary, you are required to make a resubmission to the College of Health and Social Care Research Ethics Committee.

We will also require an annual review of the progress of the study and notification of completion of the study for our records.

Yours sincerely,



Vice Chair, Health and Social Care Research Ethics Committee

Appendix 6.2: Ethical approval for Validation of PainChek® study from NHS Research Ethics Committee

07 September 2018

Miss Ivana Babicova
University of Derby
Kedleston Road
Derby
DE22 1GB

Dear Miss Babicova,

Study title:	**A Research into the Validity, Accuracy and Feasibility of PainChek - an electronic pain assessment tool for Individuals with Dementia in UK Care Homes.**
REC reference:	**18/WM/0192**
Protocol number:	**N/A**
IRAS project ID:	**223179**

Thank you for your letter of 06 September 2018, 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 Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise) .

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk .

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply t o any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non -NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [Approved ethics subject to clarification]		22 March 2018
Covering letter on headed paper [Cover letter on headed paper]		15 May 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity and insurance document]		22 March 2018
GP/consultant information sheets or letters [PoA infomration sheet]		15 May 2018
IRAS Application Form [IRAS_Form_06062018]		06 June 2018
Letter from funder [Letter from University of Derby]		
Letter from sponsor [Approved ethics subject to clarification]		15 May 2018
Letters of invitation to participant [Invitation to Participate for Power of Attorney]	1.4	06 September 2018
Other [Email from I Babicova]		23 June 2018
Other [Consent for people with capacity]	1.0	03 July 2018
Other [Demographics sheet]	1.0	03 July 2018
Other [Invitation to participate for those with capacity]	1.0	03 July 2018
Other [Supervisor CV]		03 July 2018
Other [PIS for those with capacity]	1.0	03 July 2018
Other [Supervisor CV]		03 July 2018
Other [Abbey Pain Scale]	NA	03 July 2018
Other [Supervisor CV]	NA	03 July 2018
Other [Debrief]	1.1	09 August 2018
Other [Supervisor CV]	NA	03 July 2018
Other [Supervisor CV]	NA	03 July 2018
Other [Leaflet]	1.0	09 August 2018
Other [Confirmation from PALS]	NA	
Other [GP notification letter]	1.0	09 August 2018
Other [Clarifications of application]		
Participant consent form [Consent Form]	1.5	06 September 2018
Participant information sheet (PIS) [Participant Information Sheet for Power of Attorney]	1.6	06 September 2018
Research protocol or project proposal [Research Protocol]	1.2	03 July 2018
Summary CV for Chief Investigator (CI) [CV Ivana Babicova]		22 March 2018
Summary CV for student [Student academic CV]		12 April 2018
Summary CV for supervisor (student research) [Dawn Forman CV]		22 March 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol flowchart]		15 May 2018

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

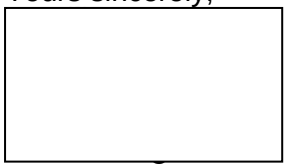
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/WM/0192 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely,

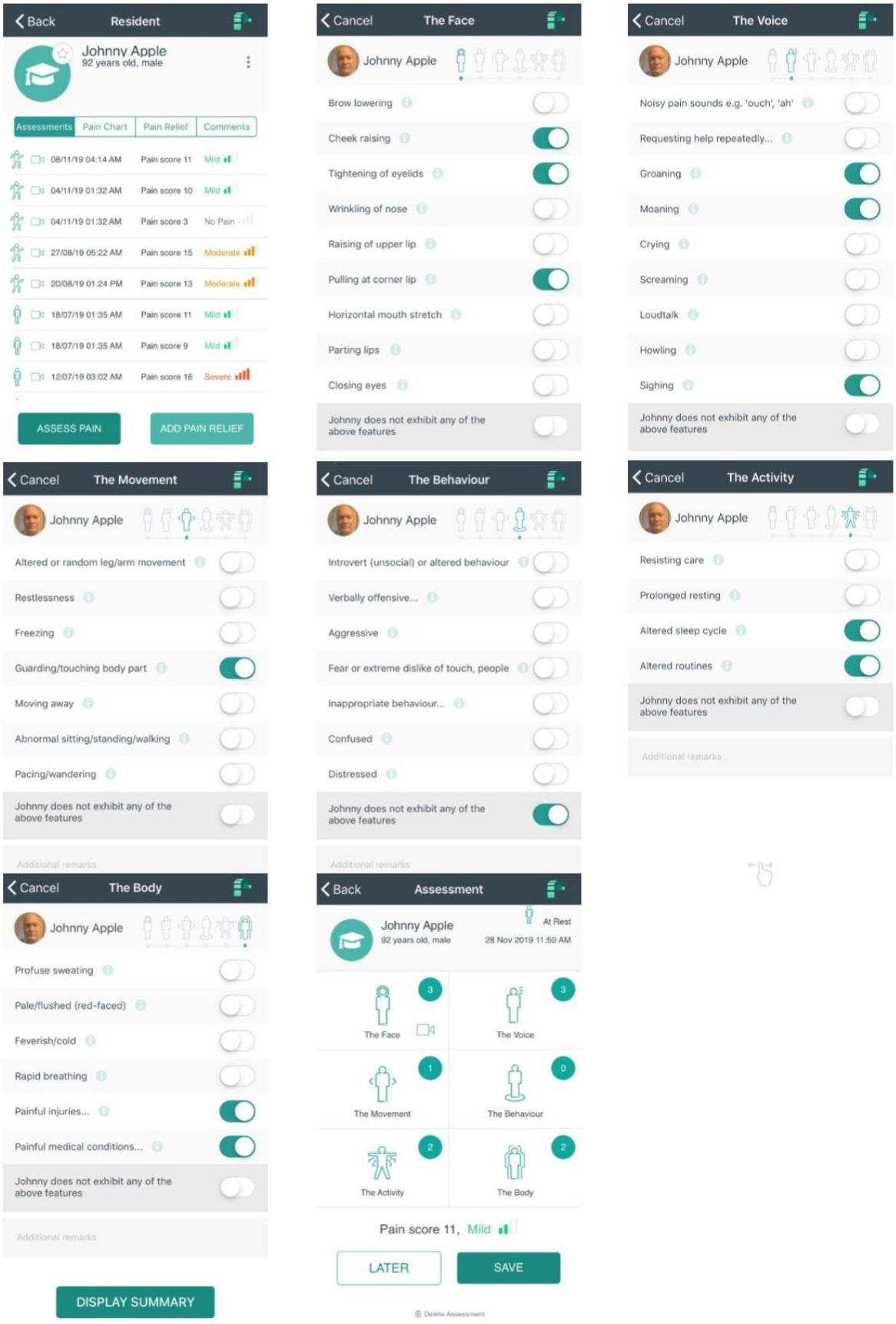


Email:NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Dr Jane Montague*

Appendix 6.3: The interface of PainChek®



Appendix 6.4: Participant recruitment and study documents (Invitation to participate, Participant Information Sheet, Consent Form and Debrief)

INVITATION TO PARTICIPATE

Dear Sir or Madam,

My name is Ivana Babicova, and I am currently a PhD Research student at University of Derby, and I am in the process of collecting data for my doctoral thesis.

I'd like to invite your relative/friend who is currently residing in a care home to take part in my doctoral project titled: **Validation of PainChek® – an electronic pain assessment tool for individuals with advanced dementia and moderate to severe cognitive impairments in the UK**. We feel your relative/friend is unable to decide for himself/herself whether to participate in this research, and therefore we would like you, as your relative/friend's consultee, to help decide whether or not they would want to be involved.

The purpose of this study is to further compare the performance a newly developed electronic pain assessment tool called PainChek® against currently used pain assessment methods. This non-invasive tool has been developed by team of researchers in Australia, and has received CE mark as a class I medical device. PainChek® is a smartphone app which utilises facial recognition technology to scan face of an individual to detect micro-facial expressions which are indicative of presence of pain. The micro-expression facial pain data are then combined with non-facial pain cues (such as vocalisation, movements and behaviour) recorded by the app user to calculate a pain score. If you would like to find out more about PainChek®, you can visit **www.PainChek.com.**

Participation in this research is completely voluntary. Whether you decide to accept for your relative/friend to take part in the research, or decline altogether your decision will not be questioned. There are no known risks to participation beyond those encountered in everyday life. Your response will remain confidential and anonymous. Data from this research will be kept in an encrypted, password protected external storage, and reported only as collective combined total. The data collection, storage, analysis and reporting will comply with the Data Protection Act (1998).

This study has been approved by the NHS Research Ethics Committee, and the University of Derby Health & Social Care College Research Ethics Committee.

If you agree to participate in this project, please let the researcher know via the email or telephone number provided below, or by contacting the care home which your relative/friend is currently residing in.

If you have any questions about this project, feel free to contact the researcher – **Ivana Babicova** via email **i.babicova@derby.ac.uk** or TEL: 01332 592549

Sincerely yours,

Ivana Babicova

Consultee information sheet in research conducted under the Mental Capacity Act (2005)

Validation of PainChek® – an electronic pain assessment tool for individuals with advanced dementia and moderate to severe cognitive impairments in the UK

We feel your relative/friend is unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information document, and a consultee declaration consent form on behalf of your relative/friend. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your relative/friend would not wish to take part it will not affect the standard of care they receive in any way.

We understand if you do not want to take on this responsibility.

Validation of PainChek® – an electronic pain assessment tool for individuals with advanced dementia and moderate to severe cognitive impairments in the UK

About researcher: My name is Ivana Babicova, and I am currently a PhD Research student at University of Derby. I am interested in improving quality of life in people living with dementia, through investigating current and future pain assessment methods. If, after reading this form, you have any further questions please do not hesitate to contact me at: **i.babicova@derby.ac.uk**

About this information sheet: The Participant Information Sheet is designed to help you decide whether your relative/friend would like to take part in this study. It sets out the purpose of the study, what your participation would involve, what the benefits and risks to you might be, what happens after the study ends, and any other information including contact details of the researcher.

If you agree for your relative/friend take part in this study, you will be asked to read and sign a Consent Form on behalf of your relative/friend as a consultee. You will also be given a copy of the Participant Information Sheet and a Debrief form at the completion of the study for you to keep.

Please make sure you have read and understood this information sheet, before signing the consent form. Your relative/friend does not have to take part in this study if you believe that for any reason they would not wish to. If you decide for your relative/friend to take part in this study, but later decide not to continue, you can withdraw your relative's/friend's data from the study without giving a reason (see **about withdrawal** section).

About the study: This study has been given ethical approval by the NHS Research Ethics Committee and the University of Derby College of Health & Social Care Research Ethics Committee. The purpose of this study is to further compare the performance of a newly developed electronic pain assessment tool called **PainChek®** against currently used pain assessment methods. This non-invasive tool has been developed by team of researchers in Australia, and has received CE mark as a Class 1 medical device. PainChek® is a smartphone app which utilises facial recognition technology to scan face of an individual to detect micro-facial expressions which are indicative of presence of pain. The micro-expression facial pain data are then combined with non-facial pain cues (such as vocalisation, movements and behaviour) to calculate a pain score. If you would like to find out more about PainChek®, you can visit **www.PainChek.com**.

About participation: If you decide for your relative/friend to take part in this study, your relative/friend will be approached by the researcher on several occasions over a period of 12-16 weeks. Each time your relative/friend is approached, this is what will happen:

1) The researcher accompanied by a care home nurse will approach your

relative/friend. The researcher will use PainChek® to identify whether your relative/friend is in any pain – this takes approximately 1-3 minutes. The nurse who is accompanying the researcher will then, within 5 minutes, use an observational pain assessment tool which is regularly used in your relative/friend's care home – this assessment will take approximately 3-5 minutes. Both of these assessments are non-invasive.

2) Your relative/friend will be asked to move a very small distance. For example, they can be asked to stand up, take a few steps, or if they are unable to do so, they'll be asked to move their arms around.

3) Step number 1 is repeated. It is important to do this, to ensure that PainChek® is able to recognise presence of pain immediately post movement, as well as while an individual is at a resting state (such as sitting or lying down).

Please note that your relative/friend will be approached multiple times every week, however never more than once per day, and never if they show signs and behaviours which might indicate that they are unhappy or uncomfortable with this process. A care home nurse will accompany the researcher at all times to ensure that behaviour which is unusual or suggests unhappiness or distress is recognised immediately. If such behaviour is recognised, the procedure will be stopped immediately and your relative/friend will be given any care they might need.

You, as the consultee, can be present during any of the 12-16 weeks of data collection period. You do not need to inform us if you'd like to be present, or when you'll be present.

To comply with University of Derby Research Ethics Policy and Code of Practice (June, 2013) and as a part of the Records Retention Policy (March 2014), all sensitive information such as data collected and consent forms will be securely stored and kept for a minimum of 6 years before the researcher is able to destroy them. The data collected from this study

About withdrawal: If you no longer wish for your relative/friend to continue taking part in the study, you have the right to withdraw on their behalf without having to provide a reason. To do so, please contact the researcher using the email or telephone provided below, quoting the unique number which is on the last page of this document.

Researcher's email address: **i.babicova@derby.ac.uk** or TEL: 01332 592549

Once the researcher has received this information, your relative/friend will no longer be included in the data collection.

About confidentiality and security: All data will be stored securely in a password protected and encrypted folder on a computer to which only the researcher has access to. The consent forms with your name and signature will be stored separately to any other information or data. The researcher will create a unique code for your relative/friend (see more in **About unique code** section), which will be used on all data sheets, to ensure

anonymity and confidentiality. Only the researcher and their supervisors will have access to collected data.

About unique code: If you decide for your relative/friend to take part in the study, the researcher will create a unique participant code for them. This will consist of the initials of the care home at which your relative/friend currently resides in, followed by a number between 001-100. This code will be written on the last page of this document.

Lastly, if you have any questions, concerns or complaints about the study at any stage,

please do not hesitate to contact the researcher.

Ivana Babicova (PhD Research Student)
College of Health & Social Care
University of Derby
i.babicova@derby.ac.uk or TEL: 01332 592549

The researchers' supervisors are:

Dr. Ainslea Cross
Academic Lead for Health Psychology
University of Derby Online Learning

Prof. Dawn Forman
Director, Interactive Leadership and Management Development
Visiting Professor, University of Derby and Chichester University
Adjunct Professor Curtin University and Auckland University of Technology

Asst. Prof. Kreshnik Hoti
Vice Dean for Academic Affairs
Faculty of Medicine
University of Pristina

Thank you for taking your time to read through this form.

Alternatively, if you have any concerns or would like to make a complaint, you can contact Dr Bill Whitehead - the Deputy Dean of Health and Social Care college at University of Derby:

Dr. Bill Whitehead
Deputy Dean
College of Health and Social Care
University of Derby
w.whitehead@derby.ac.uk or TEL: 01332 592133

The unique code for your relative/friend is:

_____

Consultee declaration/consent form for research conducted under the Mental Capacity Act (2005)

Centre Name (Location):

Participant Unique Number for this study:

CONSULTEE DECLARATION FORM

Title of Project: Validation of PainChek® – an electronic pain assessment tool for individuals with advanced dementia and moderate to severe cognitive impairments in the UK.

Name of Researcher: Ivana Babicova

Please initial each box

I, the Consultee, have been consulted about _____ participation in this research project. I have been informed about this research project and had the opportunity to ask questions and understand what is involved in this study. ☐

In my opinion he/she would have no objection to taking part in the above study. ☐

I understand that I can request he/she is withdrawn from the study at any time, without giving any reason and without his/her care or legal rights being affected. ☐

I understand that relevant sections of his/her care record and data collected during the study may be looked at by responsible individuals from the above mentioned centre or from regulatory authorities, where it is relevant to their taking part in this research. ☐

I agree to their GP being informed of their participation in the study. ☐

_____	_____	_____
Name of Consultee	Date	Signature

Relationship to participant: _____

_____	_____	_____
Name of Researcher	Date	Signature

DEBRIEF

Thank you for taking part in this study.

This study sought to further evaluate the validity and reliability in terms of accuracy, consistency, and objectivity of new pain assessment tool called PainChek® compared with standard observational pain assessment tool currently used in the UK – called Abbey Pain Scale, which is also currently the gold standard. The researcher investigated the performance of PainChek® compared to that of the Abbey Pain Scale.

Currently, the available pain assessment tools (including Abbey Pain Scale) used worldwide are not very effective at detecting and assessing pain in people who struggle to communicate or cannot communicate at all (e.g. young children, people with some learning disabilities and people with advanced dementia or cognitive impairments). Previous research has suggested that there are factors such as subjectivity and bias which often result in lack of accuracy and consistency in observational pain assessment. In addition, there is a problem of underutilisation of observational pain assessment tools for people living with advanced dementia which leads to poorer pain recognition and management.

PainChek® aims to increase objectivity and reduce bias and therefore improve accuracy and reliability during pain assessment. PainChek® has previously been validated by a team of researchers from Curtin University, Australia who have found that it is a valid and reliable tool with an excellent accuracy of 95% when compared directly to Abbey Pain Scale (Atee, Hoti, & Hughes, 2018; Atee et al., 2017b). It is important that PainChek® is further validated in the UK, to ensure that this is a globally valid and reliable pain assessment tool. Additionally, so far the tool has only been validated using Android devices, whereas the researcher in this study has used an iOS device.

Both pain assessment tools – Abbey Pain Scale and PainChek®, are used to assess pain. The pain assessment results from PainChek® will be directly compared to Abbey Pain Scale results. The nurses and care team in the care home have not been given indication of pain score which has been generated by PainChek®, only scores from Abbey Pain Scale which have been obtained by a trained nurse or care team member where used in the routine care of the participating residents.

The researcher anticipates that the results from this study will replicate those undertaken in Australia, and further demonstrate a high validity, accuracy and reliability of PainChek® compared to Abbey Pain Scale.

Thank you again for your cooperation.

If you have any further questions, please do not hesitate to contact the researcher or the researchers' supervisors:

Researchers e-mail address: i.babicova@derby.ac.uk or TEL: 01332 592549

Supervisor's e-mail address:

Dr Ainslea Cross: a.cross@derby.ac.uk
Prof Dawn Forman: dawn@ilmd.biz
Asst. Prof Kreshnik Hoti: kreshnik.hoti@uni-pr.edu

Alternatively, if you have any concerns or would like to make a complaint, you can contact Dr Bill Whitehead - the Deputy Dean of Health and Social Care College at University of Derby:

Dr. Bill Whitehead
Deputy Dean
College of Health and Social Care
University of Derby

w.whitehead@derby.ac.uk or TEL: 01332 592133

For further information about previous validation of PainChek® conducted in Australia, you can read the references below. Alternatively, you can also visit **www.painchek.com**

Appendix 6.5: Approval for data collection from a care home

Landermeads
265 High Road
Chilwell
Nottingham
NG9 5DD

T: 0115 9256996 (Direct Line to all the Houses)
T: 0115 9683888 (Enquiries/Administration)
F: 0115 9224454
M: 07876 681144
Email: ros@landermeads.com
Website: www.landermeads.com
Company No. 2207149

Ivana Babicova, BSc. (Hons).
PhD Research Student and Associate Lecturer in Psychology
University of Derby,
College of Health & Social Care,
Kedleston Road
Derby

A Research into the Validity, Accuracy and Feasibility of PainChek® for Individuals with Advanced Dementia in UK Care Homes.

Hi Ivana

It was lovely to meet with you on Sunday and discuss the above PhD project which you are doing. We feel that it is a very worthwhile and potentially influential area to be researching and we would very much like to be involved.

We look forward to working with you

Take care

Managing Director