Confused older patients' experiences of care on a specialist medical and mental health unit compared with standard care wards

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Abstract

There are concerns about cognitively impaired older patients' experiences of general hospital care. Nottingham University Hospital developed a medical and mental health unit (MMHU) as a demonstration model of best practice dementia care. This thesis describes a controlled clinical trial comparing patients' experiences of care on the MMHU to standard care wards.

Patient experience was measured using the structured non-participant observational tool Dementia Care Mapping. Observations lasted 6 hours during which a score was recorded every five minutes for the patient's mood and engagement and activity, together with incidents of enhancing and detracting staff behaviours. Noise (alarms, background noise and co-patients calling out) was recorded.

90 (46 MMHU, 44 Standard care) patients were observed between March and December 2011. At admission, most characteristics of patients on MMHU and standard care were similar. However, patients observed on MMHU had more behaviour disturbance, more often were care home residents and were less disabled than those observed on standard care. Patients on MMHU experienced a median 11% (95% Confidence Interval (CI) 2%, 20%) improvement in the proportion of time in positive mood and engagement (79% versus 68%); a median 3 (95%CI 1, 5) more enhancers (4 versus 1); a median 13% (95%CI -17%, -7%) less time noise could be heard (79% versus 92%) but a median 15% (95%CI 1, 23%) increase in proportion of time co-patients called out (21% versus 6%).

Patients on MMHU had a better experience of care than those on standard care wards in terms of their mood and engagement, number of enhancers and improved noise levels, but experienced more co-patients calling out. This is the first study measuring an intervention to improve cognitively impaired older patients' experiences in the general hospital and the first study to use the Dementia Care Mapping tool to evaluate an intervention in this setting.

Acknowledgements

Contributions to the thesis of the author

I had changed my career from Chartered Accountancy to nursing following a career break to care for my young family. My first nursing job was as a staff nurse on a Healthcare of the Older Person ward, an area I'd chosen to work in because the complexities of the patients made the work an interesting challenge and one which nurses could play a significant role. However, I found delivering an acceptable quality of care within the fast-paced environment of the ward very difficult. I cared for many patients with very complex needs, including some with challenging behavioural problems, but received no specific training either formal or 'on the job'. The patient experience of care often appeared poor. After eight months I left, dissatisfied. It was from this experience, combined with working on a related cohort study and developing the protocol for the NIHR TEAM trial that I identified the need for an evaluation of patient experience on the MMHU compared to standard care wards, as this important outcome was not being measured. Having agreed the idea with my supervisors, I developed and wrote the grant application (with support from the co-applicants). I developed the study design, did the majority of the observations (60%) and the data entry (90%) and all the data checks. I did the statistical analysis.

The patients were sub-sampled from the NIHR TEAM trial. Rowan Harwood and I developed the protocol. I produced the ethics submission with Rowan Harwood. Through discussion with Rowan, I contributed to the research design and the scales to be used. I managed the development of the randomisation algorithm and I project-managed the NIHR TEAM trial, which included managing a team of up to 10 researchers and ensuring recruitment was kept to target. I developed the system of controls to ensure complete and accurate data collection and was responsible for staff training.

A training programme was devised to develop my skill in research methods, statistical techniques, the use of specialist software and the observational

tool Dementia Care Mapping. Details of training courses attended are in appendix 1.

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Appendix

1. Introduction

This thesis reports research on cognitively impaired, older patients' experiences of care on a medical and mental health unit compared to standard care wards in a general hospital. To understand the importance of this work, this chapter has summarised the background against which this work took place. References will be cited later in this chapter. The case made in this chapter is summarised as follows. A high proportion of older people in the general hospital are cognitively impaired. Many of these patients have functional, behavioural and psychological problems which, when combined with memory loss or confusion can make the delivery of care difficult. The public and policy makers are concerned about the quality of care delivered to these patients and that their experience of hospital is poor. In the UK, person-centred care is widely considered the best model of care to ensure a good patient experience, although there is debate about how changes can be made to hospitals and staff practices to change care so that it is more person-centred. Attempts to change care by working with and training nursing staff to make care more person-centred have met with staff indifference. There is also a lack of evidence about exactly what type and duration of training is required to change staff behaviour. Two service models, liaison psychiatry services and combined medical-psychiatric units have been proposed to improve the quality of care for people with dementia/mental health problems in general hospitals. Neither has yet been shown to improve the experience of care. Locally, a randomised controlled trial (the NIHR TEAM trial) of a combined medical-psychiatric unit (called the Medical and Mental Health Unit, MMHU) was conducted 2010-2012. The aim of this thesis is to present research which evaluated the effect of the MMHU upon the patients' experiences of care.

To understand some key terms in this thesis, the next section gives definitions.

1.1. Definitions

A general hospital is one set up to deal with many kinds of disease and injury, and normally has an emergency department to deal with immediate and urgent threats to health. In contrast, psychiatric hospitals specialise in the treatment of patients with serious mental health problems who are physically well[1].

The phrase cognitive impairment includes two terms. Cognitive – 'relating to the mental action or process of acquiring knowledge and understanding through thought, experience and the senses'[2] and impairment - 'an abnormality of body structure or function '[3]. In older people cognitive impairment is commonly due to dementia or delirium but can also be due to stroke, head injury, Korsakoff's syndrome or learning disabilities.   The term 'confused' is commonly used by clinicians to describe cognitive impairment and abnormal behaviours associated with it.

Dementia is a condition of progressive, global, cognitive impairment that is sufficiently severe as to interfere with functional abilities[4]. Standard diagnostic criteria include loss of memory and at least one other cognitive function from language, executive function, apraxia or agnosia, which persists for greater than 6 months and for which no other explanation can be found [5, 6].

Delirium is an organic psychiatric syndrome- a psychological or mental response to a 'physical' cause. It comprises a transient, usually reversible state, with variable, fluctuating and wide ranging abnormalities in attention, alertness, cognition, perception, sleep-wake cycle, agitation or psychomotor retardation [4].

Many of the reports and much of the research refer specifically to people with dementia. In this thesis the term cognitive impairment is used as a generic term for all conditions which could result in confusion or memory loss, except where otherwise specified.

1.2. The Size of the Problem

It is estimated that over 680,000 people have dementia in the UK, and this figure is forecast to rise to over 1.7 million by 2051 [7].

Older people with cognitive impairment occupy a high proportion of hospital beds. The Royal College of Psychiatrists' systematic review [8] of older people in hospital cited the prevalence of dementia as 31% (17 studies, with a range of 5-45%), delirium 20% (31 studies, with a range of 7-61%). Studies which focused on patients with cognitive impairment rather than a specific diagnosis identified a prevalence of 22% (33 studies, with a range of 7-88%). The differences in prevalence are explained by different study populations, different hospital specialities and the use of different methods of assessment. Different recruitment methods and how well the informant knew the patient could also have affected prevalence results.

Establishing the prevalence of specific mental health problems of patients admitted to hospital can be difficult. Formally recorded diagnoses of dementia at admission underestimate prevalence [9-11]. Where a thorough assessment is made by a psychiatrist or geriatrician, the prevalence of dementia is approximately 40% of older people (40% of medical admissions over 65 years [12], 40% of elderly hip fracture patients [13], 40% of patients over 70 years on an acute geriatric ward [14], 43% of patients older than 75 in an acute geriatric hospital [15]). Typically a diagnosis of dementia is only recorded in medical notes or previously known about 50% of the time dementia is present [12, 14]. About half of dementia in the community is undiagnosed [16]. A recent cohort study estimated that the prevalence of cognitive impairment among people over 70 admitted to hospital was 50% [17]. Only 54% of these patients with cognitive impairment had diagnosed dementia recorded in their medical notes.

By all estimates, there are between a quarter and a half of older people with cognitive impairment in the general hospital. The next section describes the

characteristics of these patients in terms of demographics, functional ability and behavioural and psychiatric problems.

1.3.   Description of Cognitively Impaired Older People in Hospital

A cohort study conducted in preparation for the NIHR TEAM trial described the patient population for this study [17]. Patients aged over 70 who were consecutively admitted as an emergency and who appeared to have a mental health problem on screening were recruited. In summary, these patients had a median age of 86 (IQR 80-90, range 70-100). 27% were admitted to the hospital from care homes; 39% lived alone and 33% co-habited. Many of these patients were highly functionally dependent on staff for care with 31% having a Barthel Index of 0-5/20. 53% were incontinent or catheterised; 48% needed major help with transfer and 58% needed assistance with eating. For many patients, there had been a marked deterioration in functional ability since prior to the current illness (when 23% of patients were incontinent, 13% needed major help with transfer and 23% needed assistance with eating). Most (85%) were either malnourished or at risk of malnutrition at admission. 73% were on five or more medications.

Some had behavioural and psychiatric problems including delusions (14%), hallucinations (10%), agitation or aggression (17%), depression (34%), anxiety (34%), elation (2%), apathy (38%), disinhibition (10%), irritability (20%), motor behaviour problems (21%), difficulty sleeping (33%) and appetite problems (48%).

Thus, these patients with cognitive impairment had many physical and behavioural problems which, when combined with memory loss and confusion, could make the delivery of good quality care time consuming and difficult. The next two sections review literature on the quality of general hospital care of these patients.

1.4.   Dissatisfaction with Care

There is widespread concern about the quality of general hospital care of older people and specifically those with dementia. Numerous reports detail patient and carer dissatisfaction with care. These reports came from interested charitable organisations such as Age Concern (which became Age UK), the Alzheimer's Society and the Patient's Association [18-21]; the Department of Health (16); the National Health Service Confederation [22], the Older People's Commissioner for Wales [23] and regulatory authorities of the Health Services Ombudsman and the Care Quality Commission (formally the Health Commission) [24-26]. A listening event of carers, clinicians and hospital management, hosted jointly by the University of Nottingham and the Alzheimer's Society reflected these concerns [27]. The common themes from these reports were that older people, particularly those with dementia, were not always treated with dignity and respect, were not always given sufficient assistance to eat and drink, and had insufficient occupation whilst in hospital. There were also issues raised with staff training in the care of, and communication with older people with dementia, and with the hospital environment.

These reports excited much media attention. They were the source of shocking newspaper headlines: 'dementia patients ignored by hospital staff' (The Telegraph, 16 December 2011) [28]; 'Hospitals make dementia worse' (The Daily Mail, 17 November 2009) [29]. Radio programmes asked the public to phone in, who often recounted stories of the poor quality care they or their relatives received whilst under the care of the NHS, and these tended to outweigh those stories of good care. Although such media coverage does not represent a scientific measure of public opinion, or of quality of care, it points to widespread public concern.

Improving hospital care of older people with dementia is required by the English National Dementia Strategy [16] and the NHS Outcomes Framework [30]. Recently, two other areas of interest have come to the fore, both of which

bear on the care of people with dementia: an interest in the dignity of care (enshrined in the NHS Constitution [31]) and residual institutional ageism (legislated against in the Equality Act [32]). Together, these provide strong policy pressure towards ensuring improvement in the quality of care.

In response to these concerns and the policy pressures, the National Dementia Audit[33] included non-participant observations of care in 43 hospitals on 105 hospital wards. Qualitative analysis of the observations concluded that there was little evidence of person-centred ward culture or of an overall person-centred experience for patients; care was task-driven, there were periods of care based activity interspersed with long periods of inactivity, leading to lack of stimulation and boredom for patients; the environment was not dementia friendly and was impersonal with excess noise at times and a lack of orientation cues, dementia aids or areas for socialisation; there was inconsistency in the quality of communication. No hospital had all participating wards described as being person-centred.

These reports were based on a range of evidence. Audits were done by clinical staff, some reports were based on complaints or inspections which may or may not have been representative and others were by charities that may have had a vested interest in more resources being allocated to their concern. The media's aim was to sell newspapers and could sensationalise stories. To get a more objective and balanced insight into cognitively impaired patients' experiences of care, the next section reviews the research evidence in this area.

1.5.   The Research Literature

The research literature on older people with cognitive impairment in the general hospital also suggested these patients' experiences were poor. The literature identified is from the systematic review used for the National Dementia Audit (unpublished) [34] and a more recent literature review of experience of older people with mental health problems in general hospital [35]. Studies used participant or non-participant observation and/or interviews.

Many of the studies were small scale with a sample size of 15 or fewer [36-43]. Some studies were of people with dementia [36, 38, 40] others studied people with a range of mental health problems, predominantly dementia, delirium or depression [35]. Some interviewed older people who had recovered from delirium and could remember the experience [41-43].

Common themes came out of the research.

- The hospital environment

  Being in hospital was a difficult and disturbing experience for patients [36, 37]. Noise was particularly a problem [36] and some patients sought peace and quietness and wanted to be undisturbed [44]. Admission to hospital disrupted the patient's routine [35]; patients needed to adjust to an unfamiliar hospital environment [40].

- Maintaining identity

  Patients found it difficult to maintain acceptable appearance [36]. They attempted to control the care provision they experienced through actions, words and attempts at autonomy/passivity [38, 39]; staff interactions were often task orientated [36]; patients with dementia needed to feel understood by nurses [40]. Patients felt lonely whilst in hospital [41, 42]. Patients struggled to gain control over their environment [35, 44]. Patients didn't feel listened to [42]. Staff behaviour towards patients was key to the patients' experiences and could support patients in maintaining their identity, egalitarian interaction, respect and enhancement of choices [38, 39].

- Strong emotions

  Patients were often anxious and uncertain about their future [36]. Hospitals had a strong emotional impact [45]. The experience of delirium could be frightening or embarrassing [44]. When difficult experiences of the patient were affirmed and trusted by staff and relatives, the patient's

experience was positive. Acute confusion caused by delirium resulted in fear, insecurity, panic or anger and patients felt frightened or suspicious [42, 43]. Patients felt lonely as they felt they were not understood and not helped. Patients also experienced hopelessness because they felt they could not rely on family and friends who did not understand their experience. When recovered, patients felt shame, guilt and humiliation over how they had behaved, they looked for reasons to explain the episode and were fearful of recurrence of the delirium [43].

- Staff understanding the mental health problems

  Patients and their carers felt that the patient's mental health problems were not understood [35, 40-42, 45]. The best nursing practice depended on the close integration of acute medical and mental health (or dementia) care [40].

Bridge's systematic review [46] of literature on older peoples' experiences in the acute care setting (some of whom had cognitive impairment) identified similar themes: the importance of the relationships patients had with staff and others; the importance of maintaining identity and the need to be included in decision making.

The reports and research evidence summarised in this and the previous section had a strong emphasis on the psychological needs of patients, which were often not met by the hospital staff.   However, the purpose of the general hospital is more than the provision of care to meet the psychological needs of patients. The next section considers the evidence on what constitutes good quality care.

1.6.   What is Good Quality Care?

The World Health Organisation stated that 'the literature on quality of care in health systems is very extensive and at the same time difficult to systematize'. [47]. Their report 'Assuring the quality of healthcare in the European Union' reviewed the most frequently used dimensions of quality of care. Based on

dimensions of quality of care identified by Donabedian, Maxwell, the Council of Europe, The Institute of Medicine and the Joint Commission on Accreditation of Healthcare Organizations [48-52], the World Health Organisation concluded that the most useful definition of quality of care was that of the Institute of Medicine and that 'Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'. They defined the most relevant dimensions of care as: effectiveness, acceptability, appropriateness, satisfaction, and patient experience.

Donabedian proposed that quality of healthcare could be measured by evaluating structure, process and outcomes of healthcare. Donabedian's approach to describing and evaluating care has been widely accepted [47]. It is used as the framework for measuring quality in the NHS outcomes framework [30].

The delivery of quality care is a process. Patient experience of care is one of the outcomes which can be measured to evaluate the quality of care. The term most often used when describing quality care for people with dementia is person-centred care [53]. Patient-centred care was discussed at length by Goodrich and Cornwell in their report *'Seeing the Person in the Patient - The Point of Care Review Paper'*[54]. They concluded that there were many terms used to describe similar concepts including patient-centred, person-centred, family-centred, relationship-centred, patient-led, personalised, individualised, patient experience, humanity, dignity, empathy and compassion. Different disciplines preferred different terms. All the terms were complex and had more than one meaning. McCormack criticised this mixing of terminology as it did not advance conceptual clarity [55].

The term 'person-centred care' originated in the work of Tom Kitwood in the 1990's. He developed the theory of person-centred care when services for people with dementia were poor and the condition of dementia was

considered a hopeless one [56]. Kitwood's views were developed from the Rogerian philosophy of person-centred care which believed that there should be respect for the subjective experience, perceptions and inner world of the individual, based on the belief that to understand an individual required familiarity, through empathy, with that inner world and to view things as they do. The concept of 'personhood' was central to Kitwood's theory. He defined personhood as '… a standing or status that is bestowed upon one human being, by others, in the context of relationship and social being. It implies recognition, respect and trust' [56]. Kitwood started the person-centred care movement in day centres, then in care homes and mental health hospitals. Kitwood described a 'malignant social psychology' for the care of people with dementia, where their environment directly contributed to their cognitive decline. Kitwood believed that the downward process of dementia was not wholly attributed to the disease processes in the brain. The social psychology within which the patient lived, whose major component was quality of relationships, was significant. This approach placed emphasis on knowing the person with dementia and the quality of the social interactions. Kitwood's views have gained widespread clinical approval both in the UK and internationally. There has however, been some criticism of these views for being underdeveloped and not offering a framework for translation of the ideas into practice [57, 58].

Person-centred care aims to support emotional and psychological needs (for identity, comfort, attachment, occupation and inclusion) by valuing people with dementia and those who care for them, by treating people with dementia as individuals, by looking at the world from the perspective of the person with dementia and by creating a positive social environment in which the person living with dementia can experience relative well-being [59]. Valuing people with dementia needs a positive attitude from both organisations and staff. Individualised care can only be delivered if staff know about a person's biography, personality, retained abilities, health and relationships and address their needs, including their healthcare needs.

Resource is needed to collect this information. To understand the perspectives of the person with dementia, staff need training (both formal and 'in service') to understand what needs the person with dementia may be communicating by their behaviour. A positive social environment requires the opportunity for activity and socialising, an emphasis on communication and a non-confrontational approach to care. The environment needs to have places where people can socialise and staff need training in communication skills and more personalised approaches to care. Thus, to provide good quality care (the process of care) for people with dementia, there is a need for improvements to the structure of care in terms of leadership, resources, attitudes and skills as was concluded by the Care Quality Commission [25].

A major component of person-centred care is dignity. Tadd's extensive review of the literature [60] identified the key elements of dignified care which included: respectful communication; respecting privacy; promoting autonomy and a sense of control; addressing basic human needs such as nutrition, elimination and personal hygiene needs in a respectful and sensitive manner; promoting inclusivity and a sense of participation by providing adequate information to aid decision-making; promoting a sense of identity; focusing on the individual and recognising human rights. Tadd discussed Nordenfelt's [61] analysis of types of dignity: the dignity of merit (dependent on rank or position), the dignity of moral stature (as a result of deeds or achievements), the dignity of identity (the feeling of worth people have related to how they are looked upon by other people. It is attached to people as autonomous persons with a history and a future and is very close to the concept of self-respect), and the universal human dignity (pertaining to all human beings and cannot be lost as long as the person exists). Dignity of identity is threatened by illness and ageing.

Morton claimed that it is not possible to distinguish good quality care for older people from person-centred care [62]. The National Institute for Health and Clinical Excellence (NICE) stated that there is broad consensus that the principles of person-centred care underpin good practice in the field of

dementia care [63]. Most models of nursing state that they are based on person-centred care, reflecting a desire to ensure that care delivery is consistent with these principles [64]. The Alzheimer's Society has also identified good person-centred care in hospital as one of the most relevant and important areas to carers of people with dementia [65].

Five implementation frameworks have been developed to describe how person-centred care can be introduced into nursing practice [66]. Some of these frameworks are developed from observational studies of patients. The number of frameworks suggests no consensus of opinion on how person-centred care can be implemented. These frameworks have been critiqued by Dewing [57]. They are summarised below:

The authentic consciousness framework [67]

This involves the nurse understanding the patient's values and life as a whole. The framework emphasises the nurse working in partnership with the patient. It includes the need for the nurse to be flexible, to involve the patient in decisions, to be transparent, to negotiate with the patient and to be sympathetic towards the patient. It is based on research exploring the meaning of autonomy for older people in hospital settings. The research was conducted on patients with mental capacity.

The skilled companionship framework [68]

This is a complex framework for relationship-based work with patients. It requires the nurse to know and work with the patient and their family, deliver holistic care and to have the skills to think through problems or sensitive situations and to prioritise care appropriately given time restraints. The framework requires a high level of skill to apply. It has been used as part of a practice development project in an acute medical unit of a general hospital.

The senses framework [69]

This framework proposes that experiencing a 'sense' of security, belonging, continuity, purpose, achievement and significance are essential for older people, their carers and nurses to create a caring environment. The framework was based on a review of existing literature and previous empirical work by Nolan [70]. Subsequent to its development, the framework was subjected to detailed empirical study involving interactive focus groups and workshops with practitioners, carers and older people to determine if the senses captured those elements of relationships that participants considered important [71].

Positive person work [72]

This is based on the work by Kitwood and the Bradford Dementia Group. It argues for the voice of the person with dementia to be heard. It is built on 12 core elements – recognition, negotiation, collaboration, play, sensory experience, relaxation, validation, holding, giving, facilitation, creation and celebration. The model describes the care contribution of the nurses in enabling these experiences to be realised in practice. Packer advocated this model to UK community mental health nurses.

The Burford model of nursing [73]

This framework considers the life experience of the patient. It facilitates the nurse to reflect on how the patient is affecting the nurse and how the nurse's feelings about the patient might influence the relationship. The philosophy behind the model is that the health experience is always unique for both the patient receiving care and for the care giver. The model requires an understanding of the patient, the nature of the nurse-patient relationship, environmental factors and the concept of therapeutic reciprocity with colleagues. A key to the model is the assessment process and its core question of 'what information do I need to be able to nurse this patient?' Care planning is undertaken with the patient and involves the negotiation of

care inputs that reflect the individual's biography and the relationship between the nurse and patient.

Whilst some of these frameworks had been used in hospitals, none had been evaluated to see if their implementation did lead to person-centred practice [66]. Only Packer's framework (Positive person work - based on the work of Kitwood) is specifically for people with dementia. Harrison commented that there was little advice on how acute care organisations could develop person-centred care in such a high pressured setting [74]. These frameworks may help clinicians to understand the nature of good care, and identify some of the key concepts that underpin it, but they do not address the problem of delivering person-centred care in the acute hospital setting, which is fast paced, where there are demanding daily routines, limitations on the environment due to policies such as infection control [75], have a high turnover of patients and where, at times, the need to deliver care as a medical emergency supersedes the desire for care to be person-centred. The motivation of staff to change their behaviour also needs addressing. Harrison[76] used action research to improve person-centred care for older people with cognitive impairment in a general hospital and found the mixed professional group of staff who came to the project had a wide range of feelings towards the project including indifference, reluctant co-operation and complete engagement. The project was initially agreed with senior managers. Some staff felt pressurised to participate as the managers had 'signed up' the unit. Other problems included staff wanting to be 'told what to do' rather than initiating change themselves. There may be more problems to the delivery of person-centred care than staff attitude. Staff can find caring for people who are aggressive towards them difficult and an organisational focus on safety can also prevent person-centred care [60, 77]. Packer [78] commented on the lack of evidence on how to implement person-centred care including which of the care enhancement possibilities provides the greatest benefit, which training programmes and how much training is appropriate, how effective is the provision of therapies to enhance person-centred care, how can person-

centred care activities be integrated into staff's daily work and the effect staff's own complex emotions have on care delivery. Packer quotes a care worker who said "There's plenty of information and training that tells us what we should be doing; I really need something or somebody to show me how to achieve all these things in my current working environment". Acute care nurses have referred to the challenges of caring for people with dementia within the acute care environment where there is limited time and the needs of one patient must to be balanced against the needs of other patients [79].

This section concludes that person-centred care is necessary to ensure a good patient experience when patients have dementia. Person-centred care can be difficult to deliver in a general hospital. Delivery of person-centred care is a process; the structures necessary to deliver such care are leadership, resources, staff attitudes and skills. The related outcome measure to determine the success of person-centred care is primarily patient experience.

In the next section the literature on recent interventions to improve the structure and process of care (not necessarily person-centred care) of older people with cognitive impairment in the general hospital is discussed.

1.7. Interventions to Improve Process of Care and Their Evaluation

Recent reports have considered possible solutions to the care of older people with cognitive impairment and advocated the establishment of psychiatric liaison services, particularly old age psychiatric liaison. They include professional position statements (Who Cares Wins, Royal College of Psychiatrists [8]; The Academy of Medical Royal Colleges [80]); Department of Health guidelines (NICE guideline No 42 – Dementia, [63]; Everybody's Business, [81] NICE Dementia Quality Standards [82]); and Department of Health policy statements (the National Dementia Strategy [16]). However, there is limited evidence on the effectiveness of these services and such services were unlikely to have provided the continuous skill and expertise that ward based staff need to deliver nursing care and medical interventions [83].

The reports also suggested the establishment of specialist medical and mental health wards (medical-psychiatric units). Only a few such units exist in the UK, others are described in the United States, Australia, Germany and the Netherlands. Such wards have the potential to provide better quality care as they bring together a range of interventions including increasing medical and psychiatric expertise, enhancing the environment to meet the needs of older people with cognitive impairment, they are multidisciplinary in nature, they provide additional staff training, they include organised activity in the day for the patients and they have a greater focus on communication with carers and on discharge planning [84-86].

However, caring for cognitively impaired patients together in one unit could result in poorer care and a worse patient experience. Problems identified in specialist medical-psychiatric units for older people include the difficulty recruiting professionals with the requisite expertise and nursing staff skilled in medical and psychiatric nursing willing to work exclusively with dependent older people [84]; the concentration of demanding patients in one place which can result in significant strain on the nursing and medical staff and conversely, de-skilling of staff on other wards; the perceived stigma for patients of being transferred to a psychiatric ward; the influence of disturbed patients on the behaviours of other patients and problems of discharging patients who need nursing home places [85].

Person-centred care is necessary for a good patient experience of care however, a systematic review of trials to evaluate medical-psychiatric units for older people [87] reported comparative trials focussed on health outcomes or resource use such as: discharge destination [88, 89] length of index admission [88-93]; mortality [88, 89]; indicators that care had been good quality such as falls, deep vein thrombosis, chest infections and use of psychotropic medicines [89, 91, 93] and psychosocial scores [92]. None included patient experience as an outcome measure.

The outcomes and indicators of care delivery used by the NHS Commissioning Board are detailed in the NHS outcomes framework [30]. The framework has five domains:

1. Preventing people from dying prematurely;

2. Enhancing quality of life for people with long-term conditions;

3. Helping people to recover from episodes of ill health or following injury;

4. Ensuring that people have a positive experience of care; and

5. Treating and caring for people in a safe environment; and protecting them from avoidable harm.

Within the domain 'ensuring that people have a positive experience of care' are:

Section 1.2   Improving hospitals responsiveness to personal needs.

Section 1.6   Improving experiences of care for people at the end of their life.

Section 1.7   Improving the experience of healthcare for people with mental illness.

The Health and Social Care Act (2012) [94] requires patients' experiences of interventions to improve services to be included as a research outcome.

Patient experience of care is defined in three ways: by clinical effectiveness, safety and their direct experience of that care [95]. In 2011, the NHS National Quality Board (NQB) agreed on a working definition of patient experience to guide its measurement across the NHS [96]. The definition included, amongst other things, respect for patient-centred values, preferences and expressed needs (including cultural issues, dignity, privacy and independence of the patient, an awareness of quality of life issues and shared decision making), physical comfort and emotional support (to alleviate fear and anxiety). These are all areas relevant to person-centred care.

Specialist medical-psychiatric units for older people may improve patient experience of care through more expertise, better training of staff, a more

suitable environment, more organised activity, better discharge planning and a more inclusive approach to family carers. To evaluate such units it is important to include the outcome measure of patient experience of care alongside other health outcomes and resource use. The next section discusses a local intervention to improve the hospital care for older people with cognitive impairment.

1.8. Context

A specialist Medical and Mental Health Unit (MMHU) was developed as a demonstration model of best practice dementia care at Nottingham University Hospital [97]. In 2008 Nottingham University Hospital NHS Trust was awarded a grant through the NIHR Programme grants for applied research funding scheme -'Medical Crises in Older People' (RP-PG-0407-10147) in part to develop and evaluate the MMHU compared to standard care wards (the NIHR TEAM trial). The initial protocol for the evaluation of the MMHU measured whether the MMHU improved care in terms of effectiveness including 90 day outcomes of days spent at home (days not dead, in hospital or newly admitted to a care home or a change of care home [98]), mortality, length of stay, functional ability, cognition, behavioural and psychiatric problems, quality of life, carer strain and carer psychosocial health, and carer satisfaction with hospital care 1-3 weeks post discharge. Initially, there was no measure of the patients' experiences of care or the process of care.

Conclusion and Aim of Thesis

This introduction has provided evidence that the issue of the cognitively impaired patients' experiences of care is important because many older patients in the hospital are cognitively impaired and their cognitive impairment, combined with high levels of function problems and behavioural and psychological problems, makes delivery of care difficult and time consuming. The evidence suggests their experience and the quality of care they receive is often poor. Patient experience is an important dimension of care, and one included in the NHS outcomes framework. A person-centred

care approach is likely to improve the quality of care for people with dementia. Interventions, such as liaison psychiatry and specialist medical and mental health units have been developed to improve the quality of care for these patients. This included the local development of a Medical and Mental Health Unit. However, none of these interventions had included (or planned to include) the outcome measure of patient experience. Such a measure is required by the Department of Health, and would provide an outcome measure for process of care which is a key concern for patients (and their carers), the public and policy makers.

The aim of this thesis was therefore to contribute to the evidence on the improvement in the quality of experience of cognitively impaired older patients in the general hospital. This aim was achieved by comparing the experience of cognitively impaired patients on a ward which had attempted to implement best practice dementia care with those on standard care wards. Specifically, this thesis reports:

1. A discussion of how to measure cognitively impaired, older patients' experiences of care (Chapter 2)
2. A systematic search and review of a suitable tool to measure these patients' experiences of care (Chapter 3)
3. The design considerations and methods of a study comparing patients' experiences of care in a controlled clinical trial (Chapter 4)
4. The results of the study (Chapter 5)
5. The discussion and conclusion of this study (Chapter 6)

2. How to Measure Patients' Experiences of Care

2.1. Introduction

In this chapter the different ways used to measure quality of care and, more specifically experience of care are summarised and discussed. In order to assess the impact of improvements in patient experience of care it is necessary to measure patient experience of care. Patient experience is likely to be improved by good quality care. As the previous section has outlined quality of care is a complex, multidimensional concept. Currently, quality assurance processes measure patient experience of care using a number of methods. Survey techniques are used to capture this directly. The numbers of complaints made are used as indicators of bad experiences. Audit processes and a range of other quality assurance approaches are used to measure aspects of structure or process that are likely to affect experience. Research approaches have used questionnaires, interviews and observations either of patients or their carers (both informal and staff) as proxies. The following sections describe the variety of approaches that have been taken, focusing on the strengths and weaknesses of each approach to measurement of experience.

2.2. The National Patient Survey

Since 1997 the NHS has measured patient experience through the National Patient Survey. This survey is conducted by the Care Quality Commission, an independent regulator of health and adult social care in England [99]. Originally, the questions in the survey were derived from detailed qualitative work with patients. More recently, the survey has included topics of public and political interest such as waiting times, access to single sex wards and perceptions of cleanliness [54]. In 2012, NICE produced commissioning guidance on the components of good patient experience and stated that the evidence of patient experience should come from surveys and patient feedback [100]. Surveys have strengths, as they can systematically target large populations of people and allow trends to be measured over time. Results

can be compared between different healthcare institutions and benchmarked against expectations. They are a relatively economic way of evaluating a service.

However, they also have disadvantages. They can be a blunt instrument for evaluating the complexities of how care has been delivered. Goodrich and Cornwell commented [54] that politicians paint broad and ambitious visions for patients' experiences of NHS care and translate these visions into practical pledges or targets that focus on a limited sub-set of the dimensions of patient-centred care. However, from the patient's point of view, every detail of every interaction and the physical environment shapes the unique quality of the experience.

The Picker Institution reported on the challenge of assessing dignity in care for the Age UK 'Dignity in Care' report [101]. It concluded that current measures do not necessarily capture the deficit of dignity in care. The report described a secondary analysis of older people's response to the 2007 National In-patient Survey which revealed that older people tended to give more positive response to questions about whether they were treated with respect and dignity than younger people. However, these responses were contradicted by the findings of qualitative research (though the report did not identify the source of the qualitative research), raising questions about the validity of methods used for measuring experience. Reasons for this could have been that older people were less critical or more forgiving of care, or it could have been that the 'global' measures used in large scale surveys were insufficiently sensitive to pick up the nuances of a complex concept such as dignity. Similarly, research by O'Connell in Australia [102] compared responses to a patient satisfaction survey with telephone interviews and comments written on the returned questionnaire. Patients found it difficult to answer questions when many different nurses provided care, some well, some less well. This is a particularly problem when evaluating the hospital care of older people with cognitive impairment as there are already concerns over variability in delivery of care [103].

In addition, the National In-Patient Survey design does not reflect the specific needs of older people with cognitive impairment: to be socially included, treated with warmth and to be kept occupied so that they maintain their cognitive abilities, communication skills and functional independence. These are areas of significant concern to carers of people with dementia [20].

However, the main weakness of surveys is the response rate, particularly if there is differential non-response. The response rate for the 2011 National In-Patient Survey was 53% [99]. There is no published analysis of non-responders. The National In-Patient Survey for 2010 was 15 pages long and had 87 questions [104]. Older people with cognitive impairment are both vulnerable to poor quality care (due to the combination of mental health problems, disability and behavioural problems) and less able to complete an in-patient survey (due to cognitive impairment affecting memory, insight, abstract thought, communication, comprehension and age related problems such as visual impairment and arthritis).

In conclusion, surveys are not a suitable way of measuring the hospital experience of older people with cognitive impairment. They are imprecise and as a retrospective measure they are difficult for older people with cognitive impairment to complete. Rather than use surveys, the Welsh Assembly Government recommended that the process of care (dignity, privacy, appropriate space and resources for purposeful activity) and patient experience of care should be monitored by complaints [105].

2.3.   Complaints

Complaints are indicative of when the patient experience is poor. In 2010/2011 the NHS received 30,446 written complaints related to in-patient care [106]. Monitoring complaints can provide an economic way of measuring deterioration or improvements in services. Complaints can be received from the families and carers of people who are unable to complete a survey and therefore reflect the experiences of the more vulnerable patients (although 9% of cognitively impaired older people admitted to hospital have no

identified carers [17] and thus complaints are biased towards those patients with carers). Complaints can offer insight on aspects of care which are poor quality. It is however difficult to interpret complaints [24]. The volume of complaints received has been increasing steadily for more than 20 years. This increase could mean the quality of care is deteriorating or it could be related to other factors including increased volume of activity and changing expectations. It could be an indicator of wider social changes or the result of hospitals encouraging feedback and telling people how to complain [54]. Numbers of complaints may understate the level of concern over quality. The Patients Association survey of members [107] reported that 69% of its members wanted to complain about the NHS healthcare they had received over the past five years, but of these only 56% did complain, though members of the Patients Association may not be representative. The Older People's Commissioner for Wales [23] has also commented on the inadequacy of using complaints to monitor improvements in care as some patients are reluctant to complain, others cannot due to illness or have no relatives to advocate on their behalf.

Monitoring complaints is likely to show the worst care and year on year changes in numbers of complaints may be an indicator of improvements or deteriorations in care. It is important for healthcare organisations to measure and investigate complaints as a measure of the quality their service offers. However, complaints can only show improvements or deteriorations in the very worst care, they cannot measure the degree of excellence in care or typical care. Complaints alone are not a suitable way of measuring patient experience of care for trial outcome purposes as the approach is not systematic or rigorous, and is likely to include a degree of bias.

2.4.   Patient Environment Action Team

Improvements in structure and process of care may result in improvements in outcomes [52]. The English Department of Health measured how well the NHS hospital environment delivered privacy and dignity through PEAT - the Patient Environment Action Team. Aspects of PEAT were used as an indicator of

quality of patient experience by the NHS [108]. It was self-assessed and provided a framework for inspecting standards to demonstrate how well individual healthcare organisations believed they were performing in key areas. The aims of this benchmarking tool were to ensure annual improvements were made in non-clinical aspects of patient care including environment, food, privacy and dignity. The areas included under privacy and dignity were single sex sleeping areas, toilets and bathrooms to have doors which lock and all have emergency pull cords in working order and that patients should not need to walk through opposite sex areas to access toilets or washing facilities. There should be privacy for consultation, examination and treatment. Personal conversations with patients or visitors should be conducted away from the bedside or in such a way that they cannot be overheard. Patients should be able to make or receive telephone calls in private. Their personal information should be kept confidential. To ensure patients are treated with modesty, dignity and respect, PEAT requires that patients should wear appropriate clothing, should be able to follow their usual faith practices and toiletries should be provided if patients are unable to supply their own. Patients should receive the assistance they require to eat, drink or receive personal care and staff should respond quickly to requests for help. Visiting hours and numbers should be managed.

The PEAT assessment has the benefit that it may stimulate internal reflection and analysis and could be a useful approach to change management. However, because it is self-assessed it is open to bias and it does not directly measure patient experience, just the factors which may affect experience. Assessments are on a scale of 0-5 with 0 being unacceptable and 5 excellent. In 2011 the results (n=1,222) from PEAT showed that 58% of sites achieved excellent on privacy and dignity, 41% good, 1% acceptable and 0.1% poor [109]. Such high scores were in contrast to the reports raising serious concerns about dignity in hospital care for older people [21, 24, 25].

The PEAT assessment is a limited way of assessing privacy and dignity (both important aspects of good quality care). It is self-assessed and therefore

subject to bias. It is heavily skewed towards single sex accommodation, and other structural aspects of care, but does not address the psychological needs that patients with cognitive impairment have to be listened to, included, occupied, to be treated with warmth and to maintain their identity.

2.5.   Quality Indicators

Another approach to assessing quality of care is to use quality indicators such as the ACOVE-3 quality indicators for vulnerable elders [110]. ACOVE-3 quality indicators identify what treatments are given and what care is planned and delivered for various conditions. Quality indicators are also used by the NHS to measure health, performance, quality and efficiency (108). However, there are no quality indicators for patient experience specific to patients with mental health problems [108]. The quality indicators for general patient experience in hospital are largely based on the National In-Patient Survey and PEAT.

2.6.   National Audit of Dementia

A more specific measure of the patient experience and quality of care for in-patients with dementia was developed after the publication of the National Dementia Strategy [16]. The National Audit of Dementia registered one or more sites of 99% of acute care trust hospitals in the England and Wales. The audit consisted of a core audit of a hospital organisation checklist and 40 patient case note audits followed by an enhanced audit of the quality of person-centred care in selected wards. This was assessed using a ward organisation audit, a ward environment audit, staff questionnaires, carer or patient questionnaires and observations of care interactions [33]. This audit was the most comprehensive exercise in measuring the patient experience of care to date. The observations of care interactions used the structured non-participant observational tool - Patient Interactions and Environment (PIE) - which was developed specifically for the audit. During the pilot period, the team developing the tool realised that there was little consistency on what was considered good quality care and the observational audit was analysed

qualitatively rather than quantitatively. The PIE tool is not available for public use and is being subjected to further research.

2.7.   Other Methods

Robert [111] referred to a recent proliferation in methods and approaches to capture patient experiences implemented by individual hospital trusts. These include ward level surveys, interviews and focus groups, patient forums, informal feedback to the Patient Liaison Service (PALS), formal complaints, comments on websites and feedback on the performance of individual clinicians for appraisal or re-validation purposes. These methods are used alone or in combination. They form part of the hospital quality assurance process. However, they are prone to many problems that make them unsuitable as a measure in a trial. They can be insensitive (care might improve but the measure does not show it) and they are open to bias (the score might change but this might not be due to improvement in care).

2.8.   Measuring Patients' Experiences for Research

There is no "gold standard" for measuring patient experience of care for people with cognitive impairment. People with dementia and delirium have problems with memory, understanding, communication, comprehension, abstract thought and insight. These problems are compounded for some by hearing and visual problems and physical problems preventing writing (such as arthritis, fractures, Parkinson's disease and hemiplegia). To ensure rigorous evaluation of hospital ward care, the method of evaluating care must be suitable for all cognitively impaired patients cared for on that ward, not just the most able.   The people most able to comment on the patients' experiences of care are the patients themselves, their family carers and the staff who care for them. The advantages and disadvantages of seeking information from these people are discussed.

2.8.1. Interviewing the Patients

To elicit the patients' experiences on a hospital ward, one approach would be to ask the patients about their experiences of care. Tools have been developed which measure physical and psychosocial aspects of the environment from the patient's perspective, to quantify how person-centred the care is. Alternatively, qualitative interviews can be used to elicit patients' experiences of care.

Approaches to quantify how person-centred the care was from the patient's perspective have been critically reviewed by Edvardsson [112]. A literature search did not identify any research on new tools published since this review. Whilst not directly measuring patient experience, an inference could reasonably be made that the better the person-centred care experienced by the patient, the better their overall experience would be. Thus, such tools could be suitable to evaluate patient experience of care. Most tools are questionnaire based [113-115]. Some had been designed for use in settings other than the acute hospital such as De Witte's Client-Centred Care Questionnaire (client-centredness of home care for chronically ill adults) [114]. The person-centred climate questionnaire - patient version [113] was tested on patients in a short stay elective surgery hospital. The Swedish version was tested more extensively in 21 hospital wards over 3 hospitals in Sweden [116]. The ward types were not given. The patient version was tested on cognitively intact adults (mean age 53). Suhonen [117] developed a questionnaire to measure patient perceived individual care. Validity tests were done on adults being discharged from a general hospital, who were able to complete the questionnaire independently, thus excluding the more cognitively impaired.

None of these tools had been tested on patients with cognitive impairment, and none would be suitable for use with these patients due to their problems of memory, cognition, insight, abstract thought and comprehension. The only tool identified by Edvardsson which was dementia specific was Dementia Care Mapping [118]. This was also the only observational tool. It is discussed in section 3.6.2 on page 55.

There is a growing movement to include service users with communication difficulties in research and to elicit their views, even if that is difficult [119]. This challenges the common practice of service providers assuming that it is not possible to obtain feedback from people with dementia [120]. Where the service users have cognitive impairment, researchers have shown some success using qualitative interview techniques and it has been shown that people with dementia can share their experience of care in the 'here and now' and that their accounts are not influenced by a desire to please [121]. Goldsmith referred to a project by Lam [122] who interviewed 12 people with dementia who used a weekend break project and found the people were able to express their views and concerns. This research found that service users were more concerned about the psychosocial aspects of the service (belonging, companionship, feeling valued and engagement in stimulating or pleasant activities) than the physical considerations.

However, others have questioned the validity of interviewing cognitively impaired people. Lloyd's [119] literature review of attempts by researchers to interview patients with dementia identified a number of factors which could affect the credibility of their qualitative accounts. The majority of the studies focussed on individuals with early to mid-stage dementia. Lloyd summarised these concerns as problems with poor or inconsistent memory for events [123, 124], a lack of insight or awareness [124, 125], confabulated or meaningless responses [126], poor temporal orientation [127, 128], difficulty in responding to abstract questions [129-131], a tendency towards acquiescence when more direct questions were used [132-135], limited responses to open ended questions [127, 133, 134], vague and empty speech, dwindling vocabulary, and disordered speech patterns [136, 137].

When researchers encountered these problems, there was a greater risk that researcher would impose their own perceptions and interpretation onto the accounts of respondents [138]. This could compromise the aims of conducting qualitative interviews [139].

Following interviews of people with dementia in a care home Hubbard [123] recommended a combination of direct observation and interviews to be more effective. The Picker Institute [101] said that it may be important to develop alternative methods for exploring the experiences of those with cognitive impairment and these may include carers or other representatives answering questionnaires or the use of observational tools to assess dignity. Researchers need to acknowledge the diversity of the experience of dementia and in doing so, develop a repertoire of strategies that could be used with different individuals participating in a study [123].

Despite all the problems with these patients' accounts listed above, interview data might be able to illuminate the patients' experiences of their care. The UK National Health Service has not been proactive at developing and using tools to communicate with older people with severe cognitive impairment. Winner pointed out the key issue was not 'whether these users' views were important, but how we might equip ourselves better to understand and obtain them' [140].

Some researchers believe that it is possible to study the experiences of persons living with dementia in a way that is meaningful and they have achieved some success at doing this [141-143]. However, all these studies have been conducted in community settings. No research could be identified interviewing people with cognitive impairment in the acute hospital setting which has specific problems including the patients being physically ill, with delirium superimposed on dementia resulting in higher levels of disorientation and fluctuations in mood, lack of privacy, background noise and distractions and the patients being cared for in an unfamiliar and alien environment.

Goldsmith said that 'we are not yet in a position where we can generally speak easily with people with dementia all of the time, but we know that some people are able to communicate with some people with dementia some of the time'[120]. Interviewing patient's with cognitive impairment requires significant interpersonal skills and a tool box of communication methods such

as visual rating scales, photographs of hospital wards and of older people receiving care and treatment, key word prompt cards to use alongside interview questions and the use of specialist conversation aids such as 'Talking Mats' [144]. Such research is important to elicit the experiences of the patients (particularly as their views of services are so rarely sought). Interviews might offer rich data on the patients' experiences, however this is not measurement. The aim of this research was to evaluate the patients' experiences of care in two different ward settings. Patients' experiences needed to be measured so that a statistical inference could be made. There were no tools available to measure patients with dementia experiences of care and it is unlikely any such tools would be developed as:

1. Patients with dementia may be able to express opinions on the 'here and now' – but due to problems of memory, may forget what had happened earlier that day. An interview done in an activities room following an activity is likely to result in a very different interview to one by the patient's bed side.

2. The flexibility likely to be needed to interview patients with varying degrees of cognitive impairment would make comparisons of two ward types difficult.

3. Interview data, whilst providing valuable insights into the experience of the patient cannot tell us whether their experience was typical. To do this, the data has to be collected in a systematic way and on a representative sample.

4. It would not be possible to interview all patients on the wards due to severe illness, inability to communicate or extreme anxiety. However, it is important to measure the experiences of these patients. In a recent cohort study [17], 13% of patients with cognitive impairment recruited to the study had a mini mental state examination (MMSE) score of 0, 22% had a MMSE of $\leqslant$ 5 [unpublished data]. Hubbard [123] concluded that if the researchers relied only on interview as a technique for exploring quality of life in institutional care settings then the voice of those with

dementia that affected their ability to communicate using conventional rules of syntax, or their memory, would be ignored.

Thus interviewing the patients was not an option for this research study. Another possibility was to obtain information from family carers. The next section discusses this.

2.8.2. Interviewing Family Carers

A proxy measure of patient experience could come from carer interviews. Family carers are often concerned about the welfare of their relative in hospital and focussed on them as an individual. They know the patient, their preferences and beliefs and are able to communicate on behalf of the patient. Measuring the family carers own experience of the hospital may be useful in its own right. However, the view of service users can be different to their carers [145]. In addition to this, carer strain is often high and their psychosocial health poor [146]. The stress experienced by the carer may cloud their judgement when assessing the patient's experience. Auer[147] summarised why carer reports were sometimes not reliable due to the confounding effect of care giver burden, guilt, and other emotional problems related to the care-giving process. All these factors could potentially bias a care giver's subjective report. Care giver reports could be subject to two major sources of error: exaggeration and denial[147]. Similarly, carers' views may be influenced by previous, negative experiences of hospital care for their relative [148].

There is a more fundamental problem with interviewing family carers- the limitations on visiting time. Most hospitals in the UK have restricted visiting times. In the hospital where this study was conducted visiting is restricted to between 2.30pm and 8.30pm. Many visitors only visit for a couple of hours a day. Some relatives never visit in hospital. In addition 9% of older people with cognitive impairment in hospital have no identified family [17]. The majority of the nursing and medical care is delivered when visitors are not on the ward, and when a patient has visitors, staff tend not to interact to the same extent with the patient. The carers would only be aware of the patient's

reported experience of care (a potentially unreliable measure) or the patient's experience whilst interacting with the carer, again, not necessarily representative of the whole of the patient's day. Irrespective of the degree of bias carer subjective reports are likely to introduce, the carer is unlikely to be able to comment on the patient's direct experience.

2.8.3. Interviewing the Staff

Staff could be interviewed to ascertain information on the patients' experiences (an outcome measure) or the quality of care offered (a process measure and a proxy outcome measure). The ward based staff often spend the most time with the patient when they are in hospital, and are present 24 hours a day.

A number of questionnaires have been developed to measure how person-centred the environment is [116, 149]. The Person-Centred Climate Questionnaire [116] is a valid and reliable tool for assessing staff perceptions of person-centeredness of hospital environments. However, such scales are subject to bias if staff rate their own performance. Staff on a specialist ward may want to make themselves look better or alternatively, they may be more aware of the issues of delivering person-centred care and thus more critical of their skills. White [149] commented that the initial response to person-centred care was that "we are already doing that", it was often not until months after learning more about the concepts and working to implement new practices that some staff reported "we weren't as person centred as we thought". In addition, rating scales tend to be retrospective which further reduces their value for research directed at changes of experience throughout the day.

Similar problems of expectations and bias exist with qualitative interviews of staff. In addition, nurses working with older people are not always good at articulating the knowledge, skills and expertise underpinning their practice and its impact on patient care [150].

There are no scales available which act as a proxy measure of patient experience. The hospital is a fast paced environment. Hospital nurses are

often very busy. It can be difficult for nurses to notice the individual patient's experience, particularly if the patient is quiet or withdrawn. Nurses often work 'long days' (12-13 hour shifts) which mean they can have three or four days away from the ward a week. Nurses do not necessarily care for the same group of patients on consecutive days. They may have spent very little time with any particular patient to base their judgement of the patient's experience of care and are thus are not reliable informants. Using the staff as informant is therefore not a suitable way to measure patient experience.

2.8.4. Tools to Assess the Structure and Process of Care

Measurement of the structure and process of care could act as proxy measures of patients' experiences of care. Tools have been developed which assess both the environment and process of care. These include the Therapeutic Environment Screening Survey (TESS) [151] and the Professional Environmental Assessment Procedure (PEAP) [152].

The Therapeutic Environment Screening Survey for Nursing Homes (TESS-NH) is an observational instrument for assessing the physical environment of institutional settings for persons with dementia [153]. An 84 item scale measured exit control, maintenance, cleanliness, safety, orientation/cueing, privacy, unit autonomy, outdoor access, lighting, noise, visual/tactile stimulation, space/seating and familiarity or home likeness. The scale is designed to be used in nursing homes.

PEAP consists of five point ratings of nine dimensions, each of which represents a desired feature of a "quality" environment: maximising awareness and orientation, maximising safety and security, provision of privacy, stimulation and coherence, support of functional abilities, provision of opportunities for personal control, continuity of the self, and facilitation of social contact.

Whilst environmental changes had been made to the MMHU environment, there were financial factors limiting the extent of these changes. These changes have already been described in depth [97]. The layout of the ward

was similar to other wards in the hospital. In addition, measuring patient experience by measuring such structures and processes of care is a weak proxy for patient experience as improvements to the structure or process of care does not necessarily improve the outcome of patient experience of care [52].

2.8.5. Direct Observation of Care

Given the problems with obtaining information from the patient, family carer or staff, observations of care could be the most valid way of inferring patient experience. Experience is subjective. An observer can only infer experience from behaviour or demeanour. Qualitative researchers tend to treat observational methods as their "gold standard" [154]. Murphy and Dingwall [154] discussed the chain of transformation – how many times the reality was interpreted. With observations the only transformative intervention is that of the researcher. The important thing is to identify what the researcher introduces between the observed events and the published analysis. With interviews there are two transformations – how the interviewee interprets reality and how the interviewer interprets what the interviewee says. However, a disadvantage with observations is that it is not possible to understand reasons for people's actions. Donabedian [155] commented that the clinician often knows a great deal about the patient from previous contacts. This will affect how the patient is cared for, but will not be known to the observer. In addition, the observer is unlikely to be a neutral recorder and then judge of the same event. His knowledge and criteria are likely to influence what he perceives, introducing a certain distortion into perception. However, observation does enable older people with cognitive impairment who could not be interviewed or are difficult to interview due to verbal communication difficulties to be included in research [123].

Observations can be participant or non-participant, structured or unstructured. The merits and weaknesses of different methods are considered below.

2.8.5.1. Participant Observation

Participant observation involves the researcher gaining first hand involvement in the social world chosen for study. The researcher is both a participant and an observer. Immersion in the setting permits the researcher to hear, see and begin to experience reality as the participants do [156]. It has the disadvantage that the wider environment (such as what other patients are doing, other demands on staff time and noise levels) is difficult to capture and the writing of field notes will be, necessarily, retrospective introducing the risk of recall bias. The very presence of the participant observer may alter the care being given to the patient and is thus not so appropriate for a comparative study.

2.8.5.2. Non-Participant Observation

This involves observing the subject from a distance. It has been criticised for generating a 'Hawthorne effect' [157] with staff changing their normal behaviour whilst being observed. There is also the potential for bias from the observer, particularly if they have a vested interest in the success of an intervention or a point of view to advocate. This effect can be mitigated if observations are video recorded. Videoing observations has been used by researchers [158, 159]. However videoing observations can restrict what is seen, dependent on the viewing line of the cameras. Video recording patients in hospital is also unlikely to gain ethical approval in the UK. In addition, recent observations of staff behaviour [35] suggested that staff do not obviously change their behaviour when observed (as they have been observed delivering undignified care).

2.8.5.3. Structured Non-Participant Observations

Structured, non-participant observations code behaviour of interest at regular time intervals during the observation. Structured, non-participant observation tools quantify behaviour and therefore allow a statistical comparison to be made. The observations can be real-time, giving a measure of duration and frequency of behaviours, or time-sampled which is less precise, but give approximate duration and frequency [160]. The tools

themselves can be subjected to reliability and validity tests, increasing their value as research tools (see section 2.10). They do not rely on retrospective accounts or the reliability of the informant and involve only one interpretation of the reality (the observer's), which with sufficient training and testing of observer inter-rater reliability, can reduce the potential for bias. However, as for all observations, some aspects of experience will not be directly observable. Also they do not necessarily capture the subtle actions and interactions that can be important to a participant [161].

2.8.5.4. Unstructured Observations

Unstructured observations can generate rich data on the quality of care and behaviours of people, from which the patient's experience of care can be inferred. However, it is not possible to generalise the findings of qualitative research without lengthy thematic analysis and it is not good for comparative work.

2.8.6. Conclusion of Research Methods to Measure Patients' Experiences

It is not possible to elicit the experience of patients with cognitive impairment in a valid, reliable, systematic and quantifiable way. Staff and carers are unlikely to be reliable informants of the patients' experiences. This research study aimed to compare patients' experiences of care on a specialist medical and mental health unit to standard care wards. Interviews of patients, their carers and staff may give worthwhile data on that experience. Nolan's senses framework saw the patient, their carer and the staff caring for them as equally important in the delivery of person-centred care [71]. However, observations are considered the best way of measuring patients' experiences, where patients have cognitive impairment, and have the added advantage of providing a measure of process of care which would describe how the intervention worked. Real-time or time-sampled, structured non-participant observations would provide information in a systematic and quantifiable format which could be used to make a statistical comparison between two ward types.

This section concludes that, whilst it has limitations, the most effective way of quantifying patients' experiences is to use a real-time or time-sampled, structured, non-participant observational tool. The next sections discuss what behaviours need to be measured and the psychometric properties needed for the tool to be valid and reliable for research purposes.

2.9. What Behaviours Need to be Observed?

Before choosing a tool, it is important to decide which behaviours are most relevant to the patients' experiences of care. Many structured, non-participant observation tools measure behavioural and psychiatric problems such as agitation or aggression. They include the Agitated Behaviour Mapping Instrument (ABMI) [162-164]; the Agitated Behaviour Scale (ABS) [165, 166]; Cohen-Mansfield's Agitation Inventory-Revised [167]; the Disruptive Behaviour Scale (DBS) [168, 169]; the Overt Agitation Severity Scale (OASS) [170]; the Pittsburgh Agitation Scale (PAS) [171]; the Scale for Observation of Agitation in Persons with Dementia of the Alzheimer type [172]; the Empirical Behavioural Pathology in Alzheimer's Disease (E-BEHAVE-AD) Rating Scale [147]. The patients in this study had the full range of cognitive impairment and many would not have shown agitated behaviour. In a recent cohort study only 17% of cognitively impaired patients admitted to hospital were agitated or aggressive [17]. In addition, the emphasis only on 'problem' behaviours is not congruent with the philosophy of person-centred care which aims to understand behaviour as the person's attempt to communicate. To use such scales would also suggest low expectations of the success of an intervention to that of reducing of agitated behaviours rather than increasing social behaviours or an improvement in affect.

2.9.1. Activity

Lawton [173] argued that positive behaviours were indicators of positive patient experience. Positive behaviours fall into two categories: time use (independent arranging of room or possessions, engagement in organised group activity, engagement in organised physical activity, purposeful walking,

solitary activity, purposeful gaze) and social behaviour (interactions with staff, family or visitors).

2.9.2. Affect

Another indicator of positive state of people with dementia is a positive affect state [173]. However, there is a limit to how far the person's mood can be interpreted from their observed behaviours and interactions. For example, a patient sitting quietly staring into space may be bored, in a neutral state, happily reminiscing about a past event or re-living disturbing events from the past. However there is a substantial body of work that supports the view that emotional response can be measured reliably in terms of overt behaviours [174]. Gaebler [174] argued that facial expression is an important factor in human emotion; it can feed back and influence emotional experience but it is not necessary or sufficient for all emotional experience. The work of Ekman [175] has demonstrated that certain combinations of facial muscle movements are universally associated with happiness, surprise, fear, anger, sadness and disgust. People from diverse cultures recognise and use these same configurations of facial movements to convey the same emotion. However, for people with severe dementia, Norberg found there was a diminished ability to show facial expressions [176]. Asplund found that whilst fragments of expressions remained, there was no complex expression [177]. Both these studies were done on very small sample sizes (n=2 and n=4). Magai found that researchers could discriminate affect using the maximum discriminative facial movement coding system [178, 179] in dementia patients even in late-stage dementia. Lawton considered that for people with moderate to moderately severe dementia emotion could be seen through the face, the voice, the body language, the eyes, and touch [180].

2.9.3. Engagement

Level of engagement may also suggest a better patient experience. Cohen-Mansfield defined engagement as 'the act of being occupied or involved with an external stimulus'[181]. She considered engagement to be important to

relieve boredom, loneliness and problem behaviours associated with dementia and to increase interest and positive emotions. Felce [182] also commented that high engagement was associated with better social, mental and physical well-being and appeared to be a relevant outcome measure or index of quality of life.

2.9.4. Process of Care

Patients in this study could be acutely ill, dying or distressed by their circumstance. Tadd [60] commented that delivering dignified care may or may not result in a sense of dignity in the patient – she used the example of a patient doubly incontinent through illness. They may experience shame and humiliation through not having control of their bowels irrespective of how considerate and caring the nurse is. Nevertheless, the patient's experience is still likely to be better if the care is delivered in a dignified manner than if the care is delivered in a disinterested or insensitive way. This study therefore needed a measure of process of care as a proxy measure of patient experience (if the quality of care is good, it is reasonable to infer the patient experience of care is better than if the quality of care is poor irrespective of the distress the patient is experiencing).

Thus to measure patient experience for all patients in the study, there needed to be a combination of measures of activity, affect, engagement and process of care. The tool chosen also needed to be valid and reliable. The next section considers what this means.

2.10. Considerations for Tool Selection

2.10.1. Psychometrics

The selected tool needed to have good psychometric properties. Switzer commented that the willingness of researchers to develop new measures has led to an explosion of tools assessing similar constructs including "more than 3,000 assessing general or specific health status, many with virtually no reported psychometric properties " [183]. Psychometrics is a scientific field

concerned with the measurement of subjective judgements using numerical scales and the evaluation of the reliability, validity and responsiveness of such scales [184].

2.10.1.1. Reliability

Reliability is the degree to which an instrument is repeatable. There are two types of reliability - whether different raters assessing a respondent obtain the same result (inter-rater reliability) and whether the same result is observed when the rater makes a second assessment of the patient (test-retest reliability or repeatability) [185].

Inter-rater reliability

There are a number of ways of testing inter-rater reliability. Reliability of health measurements can be reported incorrectly. Pearson correlations can be reported, but the Pearson correlation reports relationship and not agreement. A better measure is the intra-class correlation, which measures the average similarity of the subjects' actual scores on the two ratings, not merely the similarity of their relative standings on the two [185]. Where scales are ordinal or nominal, Kappa co-efficient is used as it corrects for the extent of agreement expected by chance alone and removes this from the estimate. Where the scale is ordered, weighted Kappa co-efficient can be used to discriminate minor from major discrepancies [185].

Test-retest reliability

This measures whether on repeat testing, the results are the same, in the absence of real change. The notion of repeatability is central to reliability, however, differences identified repeating the test may be correctly identifying real changes in health between the two administrations [185].

For patients with cognitive impairment, test-retest validity is unlikely to be achievable due to the considerable variation seen across the day in most behaviour measurements [186]. Smallwood refers to Taylor's paper on the sun-downing phenomenon which prevents behavioural measurements being truly

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generalisable across long time periods [187, 188]. In addition, 53% of cognitively impaired patients in hospital have delirium [17]. Fluctuation in mood is one of the characteristics of delirium [4].

2.10.1.2.   Validity

Validity is the extent to which an instrument measures what it is intended to measure. There are three types of validity: content, criterion related and construct validity. Validity concerns the level of confidence that can be placed in inferences drawn from scores [185]. Assessing the validity of tools to measure patients' experiences of care can be problematic.

Content Validity

Content validity refers to comprehensiveness. It measures completeness and relevance of the items measured. Content validity can be assessed using expert and patient opinion [185].

Criterion Validity

Criterion validity considers whether the instrument correlates highly with a "gold standard"[185]. However, there is no gold standard measure of patient experience or person-centred care [112]. Where there is no gold standard measure, validity testing is more challenging and requires tests of construct validity [185].

Construct Validity

Construct validity starts with a hypothesis that the measurement being tested is associated with other methods that measure a related concept (convergent validity) and will not correlate with methods which measure different concepts (divergent validity) [185].

When testing the construct validity of a scale, the hypotheses made of associations between the scale under test and other measurements need to be made a priori. It is not acceptable to take any statistically significant correlation, however weak, and use that as evidence of construct validity

[185]. An excellent example of rigorous validation of a tool can be seen in the report on the development of the DEMQOL quality of life instrument for people with dementia [189].

Responsiveness

Responsiveness is the degree to which an instrument is able to detect clinically significant change over time [185].

2.10.2. Other Considerations for Tool Selection

In addition to being a valid and reliable tool, consideration needed to be given that the tool was suitable in the context. Considerations here were the participants' characteristics (age, gender, educational level, health status, recent life experiences); cultural context (ethnicity, cultural traditions and norms); historical context (language, knowledge base, beliefs, attitudes, values, political and historical events) and it must be feasible to administer [183].

The tool selected must also be acceptable, in the sense that it must not be too fatiguing to administer, must take an acceptable amount of time to administer and must not result in too much missing data. It must be simple to administer or training must be easily available. The language used must be understandable to the researchers.

2.11. Conclusion

This chapter has reviewed literature on possible ways of measuring patient experience, including measuring this outcome directly or as a proxy through either informants or by inference from quality of care measures. In conclusion, the best way of measuring patient experience for cognitively impaired patients in hospital is by real-time or time-sampled, structured, non-participant observation. The behaviours which need to be coded include activity, affect, engagement and process of care. The psychometric (and other) properties needed of the tool have been discussed. Chapter 3 details the systematic search and review to identify the most suitable tool available.

3. Systematic Search and Review

3.1. Introduction

Chapter 2 concluded that a real-time or time-sampled, structured, non-participant observational tool which measures patient affect, activity, engagement and/or process of care needed to be identified. This chapter describes a systematic search and review for such a tool.

A systematic search and review combines the strengths of critical review with a comprehensive search strategy as used in a systematic review [190]. A critical review critically evaluates what is of value from an extensive review of literature. There is no requirement to present methods of search, synthesis and analysis. The interpretative elements are subjective. A systematic review systematically searches for, appraises and synthesises research evidence. Reporting of search methods is transparent allowing others to replicate the process. It has the strength of drawing together all known knowledge on a subject. However, traditional systematic reviews have been criticised for restricting studies for inclusion to a single study design (such as randomised controlled trials). A systematic search and review can address broad questions and result in a 'best evidence synthesis'. However, whilst literature identified by the search strategy is subjected to critical review, the fact that the literature is not evaluated using standardised tools or checklists, can result in subjectivity being introduced to support a particular line of argument [190].

3.2. Research Question

What valid and reliable, real-time or time-sampled, structured, non-participant observational tools exist to measure the cognitively impaired, older patient's affect, activity, engagement or the process of person-centred care?

3.3. Rationale

Chapter 2 discussed the situation where due to problems of memory, cognition, insight, attention, abstract thought, comprehension and communication it is not possible to interview a representative sample of patients with cognitive impairment in hospital to elicit their experience of care. Carers only visit for a small proportion of the patient's day and the strain some experience together with previous episodes of hospital care may affect their judgement of care. Some patients have no carers. Staff reports of patient experience may be biased or based on limited observation. Ethnographic techniques do not allow a quantifiable comparison to be made between two ward types. Therefore, the most suitable way to measure patient experience of care is by real-time or time-sampled, structured, non-participant direct observation.

3.4. Objectives of Systematic Search

To identify systematically (following PRISMA methodology [191]) available tools to measure patient affect, activity, engagement or process of care for people with dementia, delirium or cognitive impairment.

3.5. Methods

3.5.1. Information Source

Papers were identified for possible inclusion by a combination of searches of electronic databases, hand searches of references lists of papers and contact with experts in the field. Systematic reviews in the Cochrane Library for rehabilitation or care interventions for people with dementia were also searched for suitable observational tools. Databases searched were Medline, AMED, EMBASE, PsychINFO, CINAHL, International Bibliography of Social Sciences (IBSS) and the Applied Social Science Index and Abstracts (ASSIA). Databases were selected based on those used by others doing systematic reviews in similar areas [46, 54, 112, 192] and available through the University of Nottingham library service. Given the paucity of studies evaluating patient experience in the general hospital, it was unlikely that many tools had been

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adapted for use in the hospital. Hence, the search was not limited to hospitals.

Searches were from inception to date and limited to English language and Humans.

Goodrich and Cornwell [54] stated that search terms for 'patient-centred' care are 'complex' and there are many different terms. The terms are poorly defined or disputed and therefore unstable. Different terms are preferred by different groups. The search term selection was based on:

1. Search terms used for systematic reviews in similar areas [46, 54, 112, 192].
2. A review of MeSH terms used for known structured, non-participant observational tools in this area.
3. American and English spellings of words.
4. A process of trial and error to ensure terms used identified known tools in this area.

For database searches of Medline, AMED, EMBASE, PsychINFO and Cinahl the following search terms and combination were used.

1. To identify the population
   Dementia **OR** Alzheimer Disease **OR** Delirium **OR** cognitive impairment.

2. To identify the process or outcome to be measured
   Affect **OR** experience **OR** behaviour **OR** mood **OR** quality adj3 care **OR** patient-centred care **OR** person-centred care **OR** relationship centred **OR** personalised **OR** individualised

3. To identify a tool
   Tool **OR** measure **OR** assessment **OR** evaluation

4. The type of tool was limited to 'observation'

5. Pain was then excluded from the search.

For the International Bibliography of Social Sciences (IBSS) and the Applied Social Science Index and Abstracts (ASSIA) the following search terms and combinations were used.

1. Dementia AND observation
2. Cognitive impairment AND older person AND observation
3. Delirium AND older person AND observation

This search strategy resulted in a high number of hits (n=2000). There were many duplicates in the database searches. Duplicates were identified by importing the searches into ENDNOTE (Thomson Reuters). Attempts were made to limit the search, however these proved too restrictive. Much of the development of relevant tools was done in the 1990's or earlier, so no limitations could be put on the search in terms of dates. Attempts to restrict the search further (by including the terms validity or psychometrics or by limiting to older people) excluded known observational tools. For the MEDLINE search (487 hits) all abstracts were reviewed where there was a possibility the paper might have been measuring affect, activity, engagement or process of care. In total 50% of MEDLINE abstracts were reviewed. This gave information on what types of titles would be of value to look at. Following this papers were rejected by review of title if the title referred to any of the exclusions listed below. The number of titles to review meant that the paper would be rejected at the earliest opportunity (ie if agitation was mentioned in the title, it would be rejected without further enquiry as to whether it was a non-participant observational tool or not).

3.5.2. Inclusion/Exclusion Criteria

Studies were included which:

1. Discussed the validity and reliability of a real-time or time-sampled, structured, non-participant observational tool.
2. Used a structured, non-participant observational tool to measure outcomes. For these studies, the validation paper was identified and reviewed.

Studies were excluded which:

1. Did not review or use a real-time or time-sampled, structured, non-participant observational tool (these tended to be qualitative studies, prevalence studies, literature which did not report a study, studies or literature related to diagnosis or imaging, tools which were not real-time or time-sampled).

2. Related to a highly specific area (pain, sleep, activities of daily living, mealtime, intensive care units, driving, oral hygiene, severe dementia, weight loss, death or palliative care, wheelchair use, marijuana, scabies).

3. Did not relate to people with dementia, delirium or cognitive impairment (multiple sclerosis, HIV, depression, Creutzfeld-Jakob Disease, stroke, schizophrenia, bipolar disorder, Parkinson's disease, autism).

4. Did not relate to older people (children, young adults).

5. Related to behaviour 'problems' (wandering, agitation, aggression, disruptive behaviour, inappropriate behaviour, resistance to care, behavioural disturbance, obstreperous behaviour, difficult behaviour, behaviour and psychiatric symptoms of dementia (BPSD)).

6. The University of Nottingham library inter-library loan service was unable to source.

3.5.3. Additional Sources of Information

1. Systematic reviews identified by the above search strategy [192, 193] were used to identify any further tools.

2. The reference lists of studies selected were reviewed for further observational tools.

3. The Cochrane library was reviewed for outcome measures used in randomised controlled trials of the rehabilitation or care of people with dementia.

4. The National Dementia Audit website was reviewed for information on observational tools identified by the audit.

5. Discussions with Rosie Woolley (University of Bradford, project manager for the observational audit of the National Dementia Audit).

3.6.   Results

The number of hits by database can be seen in Table 1. Table 2 gives a detailed breakdown of the Medline search from inception to 27 May 2012. Figure 1 gives the reasons for and stage of rejections to arrive at the final list of papers reviewed.

Table 1: Results of All Database Searches

Database	Identified	Duplicates	Rejected	Included
Medline	487	0	479	8
EMBASE	751	366	382	3
Psycho Info	475	172	301	2
AMED	19	1	18	0
Cinahl	59	40	19	0
IBSS	113	26	87	0
ASSIA	96	31	64	1
Reference lists	3	n/a	1	2
Other Sources	0	0	0	0
TOTAL	**2003**	**636**	**1351**	**16**

Table 2: Results of the Medline Search - 1946 to 27 May 2012

No	Search Term	Identified
1	Dementia/	32978
2	Alzheimer's Disease/	58349
3	Cognitive Impairment.mp	19536
4	Delirium/	4844
5	Experience$.mp	572820
6	Patient-Centered Care	8334

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7	Patient centred care.mp	362
8	Person-centred care.mp	121
9	Person-centered care.mp	72
10	Individualised care.mp	98
11	Individualized care.mp	507
12	Behaviour$.mp	147867
13	Behavior$.mp	730654
14	Mood.mp	43573
15	(Quality adj3) care.mp (searches for references where the word quality and care are within three words of each other)	120742
16	Affect/	21741
17	Patient care/	6325
18	Relationship centred.mp	21
19	Relationship centered.mp	105
20	Personalised care.mp	32
21	Personalized care.mp	163
22	Tool$.mp	290673
23	Measure$.mp	1891607
24	Assessment.mp	696749
25	Evaluation	1003113
26	Observation/ OR Observation$.mp	490128
27	Pain/	101491
28	1 or 2 or 3 or 4	101880
29	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 17 or 18 or 19 or 20 or 21	1508542
30	22 or 23 or 24 or 25	3313949
31	28 and 29 and 30 and 31	596
32	31 not 27	544
33	Limit 32 to English language and human	487

Figure 1: Flow Chart of Systematic Search


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                    ┌─────────────────────────────┐
                    │  2000 hits from searched    │
                    │         databases           │
                    │  3 from reference lists     │
                    └─────────────────────────────┘
                                 │
                                 ├──────────────►┌──────────────────────┐
                                 │               │   636 Duplicates     │
                                 ▼               └──────────────────────┘
                    ┌─────────────────────────────┐
                    │   1367 Titles reviewed      │
                    └─────────────────────────────┘
                                 │
                                 │        ┌──────────────────────────────────┐
                                 │        │ Excluded:                        │
                                 │        │ Not real-time, non-participant   │
                                 │        │ observation = 641                │
                                 ├───────►│ Specific area=104                │
                                 │        │ Not related to older people=35   │
                                 │        │ Agitation/BPSD=71                │
                                 │        │ Tool already identified=20       │
                                 │        │ Not Cognitive impairment=63      │
                                 ▼        └──────────────────────────────────┘
                    ┌─────────────────────────────┐
                    │   433 Abstracts reviewed    │
                    └─────────────────────────────┘
                                 │
                                 │        ┌──────────────────────────────────┐
                                 │        │ Excluded:                        │
                                 │        │ Not real-time non-participant    │
                                 │        │ observation = 248                │
                                 ├───────►│ Not related to older people=2    │
                                 │        │ Too specific area=22             │
                                 │        │ Agitation/BPSD=61                │
                                 │        │ Already Identified=17            │
                                 │        │ Not cognitive impairment=3       │
                                 ▼        └──────────────────────────────────┘
                    ┌─────────────────────────────┐
                    │    80 Papers reviewed       │
                    └─────────────────────────────┘
                                 │
                                 │        ┌──────────────────────────────────┐
                                 │        │ Excluded:                        │
                                 │        │ Not real-time non-participant    │
                                 │        │ observation = 20                 │
                                 ├───────►│ Too specific area=9              │
                                 │        │ Agitation/BPSD=5                 │
                                 │        │ Already Identified=13            │
                                 │        │ No validity=17                   │
                                 ▼        └──────────────────────────────────┘
                    ┌─────────────────────────────┐
                    │      16 Included             │
                    └─────────────────────────────┘
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This search identified many real-time or time-sampled, structured, non-participant observational tools which measured affect, activity, engagement or process of care.

Some tools, whilst measuring behaviours, activity or engagement had too specific a focus to be used in this study. They included a study on levels of engagement during a specific activity [194]; a tool to evaluate a garden project [195]; a tool to measure level of engagement with a stimulus [181]; a tool to measure engagement in exercise [196] and a tool to measure activity during a therapeutic activity session [197].

Some tools were designed for people with severe dementia, and were not suitable to measure the experience of the range of patients who would be in this study. These tools included Perrin's Positive Response Schedule for severe dementia [198]; the Maximum Discriminative Facial Movement Coding System (MAX) [178, 179]; Clare's AwareCare tool [199] and Norberg's Direct Observations of Movements in People with Severe Dementia [200].

Others had adapted tools identified by this systematic search, for the purposes of their own project, but with no further validity testing. Morgan-Brown referred to adapting Schreiner's tool which in itself adapted McCann's and Van Haitsma's tools [201-204]. The Greater Cincinnati Chapter Well-Being Observational Tool was adapted from Lawton's affect tool. No further validity testing was done on the adaptation [205, 206].

Some tools, whilst measuring affect, activity, engagement or process of care gave no evidence of validity of the tool they used [174, 178, 207-221].

The most commonly used tools to evaluate trials, identified by this search were: The Apparent Affect Rating Scale – which measured affect [222]. Dementia Care Mapping – which measured affect, engagement, activity and process of care [118] and the Quality Interaction Schedule (QUIS) – which measured process of care [223].

3.6.1 Evaluation of Selected Tools

Details of the tools identified by this systematic search are in the Appendix 2. This section evaluates these tools for their comprehensiveness of measure, their validity and reliability, the method of data collection, accessibility of training and feasibility of use in the general hospital.

3.6.1.1.   What the tools measured

The identified tools measured a range of different behaviours. The only tool which measured affect, activity, engagement and process of care was Dementia Care Mapping [118]. Some tools only measured a narrow range of behaviours such as Bowie and Mountain's Patient Behaviour Observational Instrument [186], Smallwood's Short Observational Tool [188] and Ward's observational scale [224] and referred to 'inappropriate' or 'negative' behaviours which does not suggest a person-centred approach. The Apparent Affect Rating Scale [222] and the Apparent Emotion Rating Instrument [225] only measured affect. McCann's time sampling tool measured a range of activity and affect [203]. Wood's Activity in Context and Time (ACT) tool measured both activity and affect [226]. Other tools measured just activity such as Van Haitsma's Observer-Behaviour Streams [204], Stewart's Environment-Behaviour Interaction Code [227], Smallwood's Short Observational Tool [188], McFaydn's Measure of Engagement in the Institutionalised Elderly [228], Ward's Observational Scale [224], Kovach's systematic behavioural mapping [197] and Norman's Quality Assessment Project [229]. Felce's Measure of Engagement in Activity just measured engagement [182].

Tools identified which measured process of care were Dementia Care Mapping (DCM) [118], the Quality Interaction Schedule (QUIS) [223] and the Person-Centred Behaviour Instrument (PCBI) [230, 231]. Dementia Care Mapping measured the process of care in terms of Kitwood's philosophy of person-centred care. Dementia Care Mapping also recorded non-interactions such as when the participant was ignored or the patient's evident needs were not met (an issue for patient experience identified by qualitative research in this

area, see section 1.5). Dementia Care Mapping had previously been identified as the only dementia specific tool [112] to measure person-centred care. The Quality of Interactions Schedule recorded process of care in terms of positive, neutral and negative interactions. It did not measure non-interactions (such as ignoring). The Person-Centred Behaviour Instrument (PCBI) measured interactions between staff and residents. There were 11 verbal categories (eg shows approval, giving choice); 8 nonverbal categories (eg resident directed eye gaze, adjusting to residents pace, proximity). The categories were derived from coding categories used in Dementia Care Mapping. The PCBI did not measure non-interactions, although in Lann-Wolcott's study it was supplemented by the Task-Centred Behaviour Inventory which measured non-verbal behaviours of staff such as ignoring and physical control. This inventory was not validated [230].

3.6.1.2.   Validity

The identified tools varied in the strength of their validation. None of the tools had strong validity, though observational tools aimed at measuring patient experience are difficult to validate (as discussed in section 2.10). Only three tools set a priori hypotheses for their validity tests (Observer Behaviour Streams [204], The Apparent Affect Rating Scale [222] and The Apparent Emotion Rating Instrument [225]). None of these tools set a priori hypotheses of the strength of the relationship, just the direction.

3.6.1.3.   Reliability

All tools showed high inter-rater reliability scores were achievable.

3.6.1.4.   Method of Data Collection

Some tools used video to collect the data [188, 230]. Videoing patients in a hospital is unlikely to get ethical approval in the UK. Others used hand held recorders [186, 204, 222, 226, 227] such as Psion Organisers. It was not clear whether the software was purchasable or was developed in-house. The other tools identified were all recorded by hand.

3.6.1.5. Training

Some tools did not give any details of training [188, 197, 223, 224, 226, 229]. Others used in-house training, but with no details given in the paper [182, 186, 204, 230]. Others detailed the training given in-house [203, 222, 225, 227, 228]. Only one tool – Dementia Care Mapping, had accredited easily accessible training via the University of Bradford [118].

3.6.1.6. Validity in a General Hospital Environment

Most tools had been validated in nursing or residential homes, psychiatric hospitals or special care dementia units. The Measurement of Engagement in the Institutionalised Elderly[228] and Norman's Quality Assessment Project [229] had included general hospital wards in their validations. Dementia Care Mapping had been validated in community settings [118], but had been evaluated for feasibility of use in the acute ward environment [232].

3.6.1.7. Conclusion

From this systematic search and review, Dementia Care Mapping was identified as the most suitable tool to use. It was the tool which most comprehensively measured affect, activity, engagement and process of care. It had been tested for feasibility in the general hospital, it had accredited, easily accessible training. It was simple to administer, using only paper and pen to record the data. The following sections look in more detail at the suitability of Dementia Care Mapping for research purposes.

3.6.2. Dementia Care Mapping

Dementia Care Mapping is done over a 6 hour period. Every five minutes a score is given (the mood and engagement score) of the person's mood (affect) and engagement level (recorded on a six point scale: +5 (very high positive mood or deeply engrossed), +3 (considerable positive mood or considerably engaged), +1 (neutral: an absence of overt signs of positive or negative mood or brief or intermittent engagement), -1 (small signs of negative mood or withdrawn), -3 (considerable signs of negative mood), -5

(very distressed, very great signs of negative mood). The mood and engagement scores are averaged to give a mean mood and engagement score as the primary outcome measure. One of 23 codes (behavioural category codes) is assigned according to what the person is doing (eating, walking, sleeping, etc. see page 87 for full list). Strict rules are applied to determine the code to give when more than one mood and engagement score could be recorded or the person is engaged in a variety of activities during the five minute period. How well the person's psychological needs are met (or disregarded) are recorded as 'personal enhancers' or 'personal detractors' as and when they occur. There are 17 personal enhancers and detractors relating to comfort (warmth, holding, relaxed pace versus intimidation, withholding, outpacing); identity (respect, acceptance, celebration versus infantalisation, labelling, disparagement); attachment (acknowledgement, genuineness, validation versus accusation, treachery, invalidation); occupation (empowerment, facilitation, enabling, collaboration versus disempowerment, imposition, disruption, objectification) and inclusion (recognition, including, belonging, fun versus stigmatisation, ignoring, banishment and mockery) [233]. Examples of these are in Tables 5, page 91 and Table 6, page 93.

Dementia Care Mapping is both a measure of process (through the personal enhancers and detractors and the behavioural category codes) and an outcome measure (the mood and engagement scores). The personal enhancers and detractors measure the balance of supportive and harmful social psychology of the environment within which the person with dementia is being cared for. They reflected many of the areas identified as important to people with dementia when in hospital (not being ignored, maintaining identity, being listened too, being included, respect, choice, validation of patient's negative experiences, needing control over the environment - see section 1.5). It is a tool widely used in mental health and care home clinical practice to measure quality of care, and thus would provide a measure of process of care.

3.6.2.1. Psychometric Properties

Sloane summarised descriptive data from several different research studies on the psychometric properties of Dementia Care Mapping [118]. All the research was done on Dementia Care Mapping version 7 (DCM 7). At the time of this research Dementia Care Mapping version 8 (DCM 8) had superseded this. DCM 8 clarified and simplified codes and introduced some new codes. It also replaced the recording of 'positive events' with a more structured recording of personal enhancers. Interviews with users of Dementia Care Mapping and staff focus groups suggested that DCM 8 was preferable to DCM 7 [234]. Mean mood and engagement scores from DCM 8 were found to correlate highly with Well-Being/Ill-Being scores of DCM 7 ($r=0.97$, $p<0.001$) and there were similar distributions of behaviour category codes. None of the validity research was conducted in a general hospital. All reliability and validity research was done on the behaviour category codes and the mood and engagement scores. None had been done on the personal enhancers and detractors.

Reliability

When used as a research tool, high inter-rater agreement was achievable. , Edelman found an inter-rater reliability (percentage of scores in agreement) of 85% [235]; Fossey a kappa of > 0.8 [236]; Woolley's [232] research on Dementia Care Mapping in an acute hospital achieved an inter-rater reliability of 78%. However, lower reliability was found for less experienced dementia care mappers. Kuhn [237] comparing experienced dementia care mappers with less experienced dementia care mappers found only a moderate agreement on behaviour category codes (68% agreement, kappa 0.54) with an intra-class correlation of 0.80 when the behaviour category codes were aggregated into those with high potential for well-being and those with a low potential for well-being. Kuhn [237] found for Well-Being/ill-Being scores an intra-class correlation of 0.70. Thornton also found an unacceptably low inter-rater reliability when using routine care staff [238]. This may have been due to

problems of training.   The work of Kuhn and Thornton emphasised the importance of training and a pilot period, prior to the main study to become skilled at using the tool and to ensure inter-rater reliability was sufficient for research purposes. Fossey found good test-retest reliability using Dementia Care Mapping [236], but the research was done in residential care facilities and such results are not directly applicable to an acute hospital setting.

Validity

All research on Dementia Care Mapping used the mean total of the mood and engagement scores (the Well-Being/Ill-Being Score) as detailed in the Dementia Care Mapping user manual [233]. However, the mood and engagement scores are ordered categorical data rather than continuous data. Calculating the mean presumes the scores are interval-level data, which may not be justified. The mood and engagement scores are also a mix of mood and engagement. Where mood is negative and engagement positive mood is scored. Where mood is positive and engagement positive, the higher scoring item is scored. This mixing up of engagement and mood further reduces the continuous nature of the scale.

None of the validity testing done on Dementia Care Mapping set a priori hypotheses, and therefore, validation against other measures must be considered weak.

Content Validity

Dementia Care Mapping's good face validity was evidenced by its widespread use as a clinical service improvement tool in care homes, mental health hospitals and the acute hospital setting. The tool was based on Tom Kitwood's (56) highly influential work on person-centred care for people with dementia. Dementia Care Mapping is internationally used as a service improvement tool with trainers in 24 countries in the world [239]. It was the tool of choice for the Australian Alzheimer's Society [240]. Dementia Care Mapping had been compared to reported experience of care from cognitively intact patient interviews. It was found to record relevant patient issues

(independence and quality of care) in a systematic way, but did not measure all areas important to patients (health status and perceived potential for recovery/returning home) [241].

Dementia Care Mapping had been used as an audit tool in a NHS Mental Health Trust [242]. It was considered as a suitable tool for the National Dementia Audit, but rejected as too resource intense [33]. Bradford Dementia Group was also commissioned by the Commission for Social Care Inspection to develop the Short Observation Framework for Inspection for use in care home inspections based on the philosophy of Dementia Care Mapping [243].

Concurrent validity

Concurrent validity for quality of life is difficult to evaluate as there is no 'gold standard' measure of quality of life in dementia. Concurrent validity has been measured against a variety of quality of life measures. Sloane reported concurrent validity measures of the mean Dementia Care Mapping Well-Being/Ill-Being score against proxy reported quality of life measures and resident reported quality of life measures in a dataset from the Mather Quality of Life study [235]. Moderate Pearson correlations (r=0.28-0.40) were found between the Well-Being/Ill-Being scores and the proxy measures of quality of life, but no correlations were found with resident reported quality of life (r=0 – 0.16). Comparisons of percentage of behaviour category codes with high potential for well-being showed similar correlations with proxy (r=0.25-0.35) and resident (r=0 – 0.13) quality of life measures. Research by Fossey [236] found strong correlations between the mean Well-Being/Ill-Being score and an informant rated quality of life measure (r=0.73, p<0.0001). There was no significant relationship between quality of life and activities (r=0.29, p=0.23).

Thornton [238] had found that the behaviour category codes were accurate when compared to Continuous Time Sampling (CTS) where the person was active, however, they under reported inactive states. This was largely due to the way behaviour category codes were categorised, where an active state

was observed in the 5 min timeframe, it took precedence over the inactive state.

Construct Validity: Converging/Divergent Validity

Dementia Care Mapping's construct validity had been demonstrated in studies in which cognitive impairment, functional impairment, social withdrawal, agitation, depressive symptoms and a number of co-morbid conditions had significant negative associations with Well-Being/Ill-Being scores (convergent validity), whereas age, gender and race did not (divergent validity) [118]. There was a significant relationship between Well-Being/Ill-Being scores and a care dependency scale. However most of the variance in Dementia Care Mapping scores was not explained by standard measures of resident characteristics (divergent validity) and therefore Dementia Care Mapping may measure additional components of quality of life perhaps reflective of care and demonstrated discriminant validity [118].

External Validity

Comparisons of data from various facilities found that Dementia Care Mapping scores tended to be higher with less restrictive care environments [118].

3.6.2.2 Use of Dementia Care Mapping in Research Trials

Dementia Care Mapping has been used as a research tool for intervention trials. Beavis's [244] literature review of Dementia Care Mapping studies to evaluate quality of care and well-being of people with dementia in formal care settings identified that whilst Dementia Care Mapping differentiated between different settings and interventions, there were many methodological limitations to the studies including inadequate sample size, short evaluation periods and a lack of consideration of the confounding variables commonly associated with dementia.

Trials included group reminiscence [245], aromatherapy [246], sensory stimulation groups [247], intergenerational programmes [248] ,outdoor activities

[249], and gardening therapy [250]. It has also been used as part of the evaluation of larger scale changes in therapeutic regimen, for example a liaison psychiatry service [251], a placebo controlled neuroleptic discontinuation study [252], a pilot of a person centred care intervention [253] and as part of a multi-method evaluation of an independent dementia care service [254]. Dementia Care Mapping had been used to evaluate the effect of paracetamol on behaviour and well-being in a randomised, double-blind, placebo-controlled, cross over trial [255]. Chenoweth and Jeon's pilot of a person-centred care intervention using Dementia Care Mapping as one of the outcome measures rejected Dementia Care Mapping for the main trial in favour of other validated informant rating scales and the Quality of Interaction Schedule, [223, 253].

3.6.2.3 Limitations of Dementia Care Mapping

Item distribution

Sloane et al [118] found little variation in mood and engagement scores across all facilities with the majority of observations assigned a +1 score. They also found that many of the behaviour category scores were not used. Dementia Care Mapping scores neutral mood as +1, sustained engagement or very positive mood as +3. Such scores should be responsive if the intervention was sufficient, particularly as a proportion of the people being observed in this study would only have mild cognitive impairment. The lack of variability in scores may be more related to the poor quality of dementia care than the Dementia Care Mapping tool itself.

3.6.2.4 Resources

Training to use Dementia Care Mapping is mandatory[256]. It involves a three day training course for basic training and a four day training course for advanced training (required for research purposes). The training is high quality with Dementia Care Mapping certification only available through licensed trainers who had undergone rigorous preparation for their role and using standardised training methods prepared by the University of Bradford.

Dementia Care Mapping is resource intensive requiring six hours per observation. Such a tool limits the possible sample size and thus the power of any study, and limits the opportunity for repeated tests on individuals. The length of the observations requires sustained concentration and can be physically uncomfortable for the observer [161]. Research by Fossey to establish if the length of observation could be reduced [236] found significant correlations between overall proportion of time in an active state and activities (r=0.68, p=0.001) mean Well-Being/Ill-being score (r=0.50, p=0.02); and +3 mood and engagement scores (r=0.94, p<0.0001) for the hour before lunch, suggesting that the hour before lunch could be representative of the six hour period. In contrast, Fulton's [257] research attempted to reduce the duration of Dementia Care Mapping and found that none of the shorter models were adequate in estimating individual Well-Being/Ill-Being profiles of the full model. Furthermore, the shorter models were not tested in a hospital environment, where the profile of activity in a day may be very different to a care home setting.

3.6.2.5 Limitations of Coding

Dementia Care Mapping was developed as a service improvement tool, and as such there are limitations as a research tool. There are also limitations with coding including the fact that coding was based on western concepts of well-being. Capstick [161] questioned the use of the code C (being totally uninvolved and disengaged from the environment) as withdrawn which does not allow for the possibility that the person is in a meditative state. As with all structured tools, Dementia Care Mapping does not capture the subtleties of action and interaction and significant events cannot all be coded in the five minute time frame. Innes and Kelly [161] commented that much more work needed to be done in order that positive person work could be documented and evaluated to the same extent as personal detractors (though this has been achieved to some extent by the development of DCM 8).

Dementia Care Mapping as a research tool has its critics. Edwards and Fox [258] stated that Dementia Care Mapping alone is insufficient to measure quality of care. They also criticised researchers making observations within office hours and then making inferences from these across the whole 168 hour week.

3.6.2.6.   Practicality of Dementia Care Mapping

Research on the experience of Dementia Care Mapping users in the United States and United Kingdom found that users could be uncertain about the Dementia Care Mapping rules with 36% (31/86) finding the rules difficult to apply [259].

Conclusion

The most suitable tool for this study was Dementia Care Mapping as it was a person-centred tool, which measured patient experience by measuring patient's mood (affect), engagement, activity and the quality of staff interactions from a person-centred perspective. Dementia Care Mapping was feasible to use in an acute hospital and the training in Dementia Care Mapping was easily accessible. However, sufficient time was needed to ensure the researchers were skilled at Dementia Care Mapping and consistently applying the coding prior to starting the main trial. Observations needed to cover the majority of the waking day for patients and not just office hours. Chapter 4 details the design considerations and methods for the structured, non-participant observational study.

4. Methods

4.1. Introduction

This chapter describes the research design, the sampling strategy and selection criteria, the measurement tool, the ethical considerations, the statistical analysis planned and the pilot period. The specialist MMHU was subject to evaluation by controlled clinical trial, the NIHR TEAM trial [260]. This study complemented other health status outcomes in this trial. The patients observed for this study were randomly sub-sampled from the NIHR TEAM trial.

Randomising patients to wards in an NHS hospital was challenging. Alternative study designs, work done and pragmatic decisions made to ensure random allocation of patients are discussed. The design of the NIHR TEAM trial was influenced by the lessons learnt from a related cohort study, conducted in the same hospital and with similar patients, which served as a pilot for recruitment and data collection methods [17].

4.2. Methods

4.2.1. Study Setting

The study was set in a large secondary/tertiary 1100 bed teaching hospital providing sole general medical services for its catchment population.

4.2.2. Study Population

The study population included patients admitted to the Acute Medical admissions Unit (AMU) of the Queens Medical Centre campus of Nottingham University Hospital NHS Trust who were aged 65 or older, and assessed as 'confused' by the clinical team responsible for their care. 'Confusion' was not further defined. The term 'confusion' was used to allow identification and referral of suitable patients by non-specialist admissions unit staff, without causing any delay to the admission pathway. The term 'confusion' was frequently used by clinicians to describe patients with a variety of mental

health problems, but who in practice, almost all had dementia and/or delirium.

Patients were admitted to the hospital by self-referral or by calling an ambulance (999) and being admitted through the Emergency Department or by referral of their General Practitioner (GP) as a medical emergency that could not be dealt with by community health services. Patients were assessed and triaged by a senior physician (not necessarily specialising in the care of older people) and patients were either admitted to a hospital ward or discharged back to community services.

4.2.3.   The Intervention and Control

4.2.3.1.   Control- Standard Care Wards

'Standard care' wards included five specialist acute geriatric medical wards, and four general medical wards (respiratory, diabetes, gastroenterology or rheumatology as their sub-specialist interests). As a matter of policy, the hospital tried to avoid placing confused older medical patients on surgical wards or transferring them (as 'sleepers out') after admission.

Most wards were 28 bedded. Beds were arranged into four bays of 6 patients, with an additional three to four individual or double side rooms. All wards would have clinical areas for medicine preparation and storage, offices for the senior nurses, the multidisciplinary team and a staff room. All wards had a reception area at the entrance to the ward. Entrance to all wards in the hospital was controlled by swipe card access. See Figure 2, page 68, for the layout of a standard care bay and MMHU bay.

Once on the ward the patient was cared for by a multidisciplinary team. This could include doctors, nurses (both ward based nurses and specialist nurses), occupational therapists, physiotherapists, speech and language therapists, dieticians and pharmacists. The professional team was supported by healthcare assistants (who provided personal care to patients and did some physiological observations), domestics (who cleaned the ward and served

drinks and meals), porters, receptionists, discharge coordinators (an unregistered administrative role mainly liaising with families, community, social services and care homes regarding discharge arrangements) and security personnel. Social workers, employed by the local authorities could also come and assess the patients. The patient could be visited by hospital volunteers or the chaplaincy.

The nurses and healthcare assistants had the most direct contact with patients. They mostly worked 'long days' which lasted 07:00-19:30 or 19:00-07:30, with two thirty minute breaks.

The nurses planned, assessed, implemented and evaluated care for their patients using an adapted version of Roper's Activities of Living Model [261]. This is a holistic model of care based around the assessment and management of the patients' abilities to carry out activities of daily living. There are five dimensions to the model: physiological, psychological, socio-cultural, politico-economic and environmental. Patients are assessed in 12 activities of daily living: maintaining personal safety; communication; breathing; eating and drinking; elimination; washing and dressing; controlling temperature; mobilisation; working and playing; expressing sexuality; sleeping; and death and dying.   Whilst cognition and behaviour had the potential to affect all these activities of daily living, they were not explicitly assessed. Therefore the focus was more on physical than mental health needs.

Complex discharge planning and assessment for rehabilitation was supported by a separate multidisciplinary advice team. Mental health support was provided on a consultation basis by psychiatrists from a separate NHS organisation (Nottinghamshire Healthcare NHS Trust). Acute geriatric medical ward practice was based on multidisciplinary comprehensive geriatric assessment, and many staff had considerable experience, and varying degrees of expertise, in the management of delirium and dementia. These wards provided most of the 'standard care' for cognitively impaired older people.

Acute and general medical wards specialised in one medical discipline (diabetes, rheumatology, respiratory medicine) but also took general patients. All wards had access to allied health professionals, social care and the intermediate discharge team, but tended to work more to a 'medical' model.

Some standard care wards had access to day rooms, but the majority had no such facilities. Wards with day rooms rarely used them for anything other than occasional television watching. There was no specific provision for organised activity on the standard care wards. There was little of interest in the environment of standard care wards and all bays look very similar to each other. Some standard care wards played modern radio music for most of the working day.

All staff in the hospital were required to follow the Trust values and behaviours which were set out in a report for staff 'We are here for you. Behavioural standards for everyone at Nottingham University Hospital' [262]. These values were aimed at improving patient experience. Under the theme 'thoughtful patient care' staff were required, amongst other things, to be 'polite, helpful, listening, compassionate and to value patient's time'. At interview applicants were asked questions to test their understanding of the Trust's values and successful applicants were educated in the Trust's objectives during their induction training. Staff were required to attend mandatory training (moving and handling, infection control, life support, child protection and conflict resolution). This training did not at that time include any reference to the additional problems of caring for people with cognitive impairment.

During the trial, in response to the National Dementia Strategy [16], the hospital Trust was developing a strategy of improvement in dementia care, to which members of the MMHU staff contributed. Other hospital staff were aware of the MMHU, and may have attended teaching or presentations related to the MMHU. The hospital ran a two day training programme in

collaboration with the Alzheimer's Society on the hospital care of patients with dementia for selected nursing staff (Dementia Champions). Person-centred care was included in this training. Following the training, the staff attending were required to do a project to improve dementia care in the hospital.

Figure 2: MMHU and standard care bays

Standard Care Bay   MMHU Bay

4.2.3.2.   Intervention – Medical and Mental Health Unit

The intervention comprised the 'package' of care delivered on the MMHU. This represented a complex intervention similar to that provided on stroke units for stroke patients. The MMHU was developed over 21 months prior to the commencement of this study. The unit was previously a 28-bedded acute geriatric medical ward. The development and philosophy of the ward is described elsewhere [97]. The MMHU had all the components of standard care wards described above, but with enhancements. In brief, five components were enhanced:

- Staff numbers and skill mix: Specialist mental health staff additional to the normal ward complement of medical, nursing and therapy staff (all of whom were experienced in working with older people), comprising 3 registered mental health nurses, a specialist mental health occupational therapist (OT), 0.5 whole time equivalent (WTE) specialist physiotherapist, 0.2 WTE speech and language therapist, 0.2 WTE additional geriatrician time and 0.1 WTE psychiatrist time, and four unregistered health care assistants, three of whom took the role of activities co-ordinators. New documentation was

introduced for mental health assessments and Occupational Therapy interventions.

- Training for all staff in the philosophy of person-centred dementia care. This emphasised respect for the person with dementia as an individual with a history, values and preferences, and the right to make choices. Confrontation was avoided, and activity and diversion promoted, recognising and exploiting the person with dementia's retained abilities. Training was done through 'time out days' and ward based training. All ward based staff were expected to attend. The training was planned and initiated by Professor Davina Porock (Professor of Nursing Research at the University of Nottingham School of Nursing) and continued by a deputy ward manager, the senior mental health nurse and the specialist allied health professionals recruited as part of the trial research programme. Specialists in person-centred care were hired to provide training sessions during the time out days. One of the deputy ward managers created a resource library, posters and leaflets for staff to understand commonly occuring person-centred and non-person-centred care scenarios. The training and emphasis on person-centred care was a continuous process throughout the trial.

Some staff attended external training courses on person-centred care. Two members of the senior nursing staff completed Bradford Dementia Group's Basic Dementia Care Mapping training. Three members of staff (two mental health nurses and a staff nurse) had completed Basic Dementia Care Mapping training several years ago. Three members of staff attended a Bradford Dementia Group person-centred care course. The senior mental health nurse conducted one Dementia Care Mapping observation on the MMHU, but the results were never fed back to staff.

A personal profile document (About me) [263] was developed, adapted from the Alzheimer's Society 'This is me' document [264]. It was designed to be completed by the patient's family carer and gave a description of the patient's needs, preferences , likes/dislikes, significant people, places and pets in their

life and interests. The document was kept at the end of the patient's bed for use by all staff.

- There was a programme of organised activities carried out by the activities coordinators under the direction of the senior occupational therapist. The activities were aimed at maintaining patients' abilities, preventing distress behaviours, and promote night-time rest. A day room was converted to an activity room. A variety of games, puzzles, music CD's, DVD's, musical instruments, reminiscence material and a Nintendo Wii were purchased. Activities regularly included bowls, reminiscence, music and singing, ball games, creative activities such as painting, quizzes and games. All patients' abilities were assessed using the Pool Activity Level Assessment tool [265]. This tool was used to identify the level of ability of people with cognitive impairment so that activity or occupation could be designed for them at the right level of ability. There were four levels of ability: planned, exploratory, sensory and reflex. A weekly programme was devised of varied activity and advertised via notice boards on the ward. A breakfast club was started where patients could make and eat breakfast, away from the busyness of the ward and at a laid table with newspapers. Patients were got up and dressed, if not too ill.

A sensory room was available for the less able patients.   The sensory room had comfortable seating for up to three people. It contained a projector wheel that displayed either countryside or a seascape which projected onto a wall, a fibre-optic spray that changed colour and could be handled, a 3 foot bubble tube which also changed colour and a compact disc player and selection of classical and instrumental music. There were also a number of tactile sensory objects which could be used either in the sensory room, by the patients' beds or in the day room.

- The environment was made more appropriate. The ward had to relocate after nine months of development, to one which was longer and with better lay out, when it was realised that sufficient adjustments could not be

made in the original one. Noise from equipment alarms was minimised. Radio was banned. Orientation cues, appropriate signage and some safety modifications were made. Bed spaces were personalised by obtaining new bedside lockers and installing glass fronted 'memory boxes' for photographs or small personal items. The ward bays were painted in distinctive colours to help patients to orientate themselves. A photographer was commissioned to take naturalistic photographs which showed positive images of the patients on the ward and the staff caring for them. These were displayed throughout the ward. Light boxes were bought displaying colourful pictures of flowers or landscapes. Sofas, tables and chairs were put at the end of each bay and throughout the ward to give the patients options of where to sit and to facilitate social groups forming away from the bedside. Clinical areas were secured with combination locks. The main entrance/exit already required swipe card access.

- A proactive and inclusive approach to family care givers was promoted, with active communication, involvement in decision making, and inclusion in hands on care, if able and willing. A document 'Caring Together' was introduced where carers could give details of how involved they wished to be with caring for their relatives whilst they were in hospital, and under what circumstances they wished to be contacted.

4.2.3.3. Contamination

The MMHU provided an expert resource used by the rest of the hospital. The mental health nurses and senior nurses on the ward would assess patients on request on other wards so long as they were not part of the controlled clinical trial. Some nursing, allied health professionals and medical staff work across wards. This included nursing staff who did agency work on other wards or where staff were required to cover shortages elsewhere. Medical staff doing out of hours work. Staff who moved jobs or were rotated off the ward. Some allied health professionals did not work exclusively on MMHU.

Many hospital-wide policies covering areas such as nutrition, mental capacity, infection control, continence, falls prevention and medicines management were of great relevance to patients with delirium and dementia, and these were promoted on an on-going basis. The trial was conducted at a time that hospital trusts were required to respond to the National Dementia Strategy [16] and there was a focus on hospital care of older people with cognitive impairment. However, it was also a time when there were intense financial pressures in the hospital resulting in restrictions on employing temporary (agency) staff and overtime and intense bed management pressures, limiting what could be achieved in practice.

This trial therefore represented an evaluation of the additional benefit of care in a geographically-defined unit, with additional staffing and training, and following best practice, beyond that achievable in standard hospital care.

4.2.4. Conducting a Randomised Controlled Trial in a NHS Hospital

This controlled clinical trial approximated to a randomised controlled trial. Conducting a randomised controlled trial in the acute medical setting of an NHS general hospital was challenging. Several alternative study designs were considered.

1. 'Conventional randomisation': suitable patients would be identified on the acute admissions ward (AMU), or elsewhere. These patients would be assessed for suitability, invited to take part, informed consent or consultee agreement sought, baseline data collected, then randomised and assigned to the allocated ward. This study design carried both the likelihood of unacceptable delays on the AMU, and empty beds on the MMHU (whilst awaiting a patient who is suitable, and recruited) especially at nights or weekends.
2. 'Tertiary referral'. No patients would be directly admitted to the MMHU. All patients would be first admitted to a standard care ward, referrals of suitable patients to the trial sought, and patients and carers then invited and consented, baseline data collected, randomisation performed, and

those allocated to the MMHU transferred. This study design would require a robust referral system (which had proved hard to develop), carried a high risk of empty beds on the MMHU, and necessitated an additional ward transfer for confused patients, which was clinically undesirable.

3. Zelen design [266]: consent sought from the 'active treatment group' prior to transfer to the MMHU; standard care group consented to follow up only. This carried the same disadvantages as conventional randomisation.

4. Smaller ring fenced number of 'trial beds' on the MMHU. This would have some of the disadvantage of conventional randomisation, and in addition would likely attract the most behaviourally disturbed patients to the non-trial MMHU beds, so distorting the standard care group.

These designs were considered unlikely to succeed or were unacceptable to Trust operational managers. The study design had to accommodate the constraints of an acute medical service very pressed for bed availability, and under rigorous performance management of patient flows, in particular, the government-prescribed maximum four hour Emergency Department wait target. This stipulated that all patients must be assessed, treated, and discharged or transferred from Emergency Departments (ED) within four hours of arrival. This, in turn, put pressure on Acute Medical Admissions Units, who must have empty beds to accept transfers from ED, and on wards to have capacity to accept patients from Admission Units.

It was unacceptable to the clinical service for potential trial participants to remain on the Acute Medical Admissions Unit whilst awaiting research assessment or recruitment procedures, or for there to be more than three empty beds on the MMHU. Patients had to be admitted to the MMHU 24 hours a day and seven days a week, regardless of researcher availability. MMHU had also to be kept full with appropriate patients. Proper time for consultation, consent or consultee agreement for research participation to be given, was necessary for ethical reasons. The consultation and consent

process for research would take longer than the clinical processes for swift bed management. So it was impossible to run a conventional randomised controlled trial with recruitment prior to allocation: clinically patients had to be allocated before they could be recruited.

Previous work demonstrated that 50% of acute medical patients over 70 had cognitive impairment [17] far more than could be accommodated on a single ward. Some allocation mechanism was therefore required by the clinical service. In usual clinical practice, ward allocation was largely driven by bed availability (described by an Admissions Unit ward manager as 'as good as random'). The service therefore agreed to allocate suitable patients at random, either to the MMHU, or standard care on another general or geriatric medical ward with broad eligibility criteria (confused, over 65, and not fulfilling exclusion criteria). This research design represented an imperfect randomised controlled trial, since some randomised patients would not agree to take part, or their carers would decline consultee agreement.

The main scientific concern about the design was failure to recruit a patient after randomisation. This introduced the potential for bias (for example, if it proved easier to recruit from one setting than the other). Despite the risk of differential recruitment bias, an important consideration was that this design enabled a trial to be undertaken at all. A conventional randomised controlled design would either have failed because of conflict with the demands of the clinical service, or would have recruited an unrepresentative population. However, the study approximated to a pragmatic, parallel group, randomised controlled trial. At the request of the study sponsor (University of Nottingham), due to liability insurance purposes, the trial was called a controlled clinical trial rather than a randomised controlled trial.

4.2.5. Inclusion Criteria

Patients were included in the study if they were

- Confused and 65 years or older.

- Referred by the Acute Medical Unit

4.2.6. Exclusion Criteria

Patients were excluded if:

- They were severely medically ill, requiring intensive monitoring or therapy (critical care), or sub-specialist medical intervention (e.g. severe acute gastrointestinal bleeding, respiratory support).
- They had an overriding clinical need for another service, such as orthopaedics, or acute stroke.
- They had acute intoxication or overdose.
- They were those detained under the Mental Health Act.
- They were admitted to the MMHU or standard care, but had not been randomised.
- They were resident outside of Nottingham City or Nottinghamshire County Primary Care Trust (PCT) areas.
- They were unable to speak English and with no available family or other non-professional translator.

A family member or carer participant was recruited where one was available and willing, to act both as an informant, and in order to study impact on carer health. A carer was defined as a non-professional, who saw the patient at least once a week, most weeks, for a minimum of one hour.

4.2.7. Randomisation

Potentially suitable patients were referred to MMHU by clinical staff on the Acute Medical Admissions Units, usually within 24 hours of admission. MMHU would only accept referrals if a bed was available at the time of the referral. All referrals were entered on to a computerised screening log, hosted by the Nottingham University Clinical Trials Unit.   A computerised algorithm was developed to allocate patients and manage beds (Figure 3, page 78). The algorithm was refined over several months of piloting. The underlying

principle was that any patient recruited into the study would have been randomly allocated to the MMHU or standard care. To keep the ward sufficiently full, some patients were admitted to the MMHU without being randomised, but these were not eligible for study recruitment. The precise details of the algorithm reflected local geography, service demands and patients admission rates, taking account of day-to-day variation in both bed availability, and presentation of suitable new patients. The algorithm was modified during the trial to ensure referrals were sufficient for the trial to recruit to target. Initially:

- Randomisation could only take place if there was a bed available on the MMHU (if not, the patient was non-randomly allocated standard care, and was not eligible for trial inclusion at this time).

- The last 2 beds on the MMHU were always available for randomisation with the exception of patients referred between midnight and 7am (relatively few patients, to avoid difficult negotiation with bed managers overnight).

- If there were 4 or more beds available on the MMHU, patients were admitted from the Acute Medical Admissions Units without randomisation; (these patients were not eligible for trial inclusion).

- Patients were also admitted to the MMHU without randomisation (and were not eligible for trial inclusion), if there were 3 or more beds available, and if referred from psychiatric wards or referred from other hospital wards, following assessment for suitability and if not previously randomised to standard care wards.

- Patients resident outside the Nottinghamshire Primary Care Trust areas were admitted to MMHU (and were not eligible for trial inclusion), if there were 3 or more beds available and if not previously randomised to standard care wards.

Prior to the start of the trial the algorithm was thoroughly tested by entering dummy data of all possible combinations of patient details to ensure they were correctly allocated (including on a night shift). All errors were corrected by the Clinical Trials Unit manager who programmed the algorithm and the relevant tests were re-performed.

Figure 3 Algorithm to Allocate Patients to MMHU or Standard Care

Enrol participant

Previously enrolled — yes → Previously randomised — yes → Randomisation code <4000 — yes → Show previous details

no

no

no

Age>=65 — no → Reject

yes

Clinically appropriate — no → Assign standard care with code > 4000

yes

MMHU Bed available — no → Assign standard care with code > 4000

yes

Night 0-7am — yes →

no

≥4 beds available on MMHU — yes →

no

RANDOMISE code <4000

Referral from admissions unit — yes → Appropriate postcode — yes →

no

no

Assign MMHU with code > 4000

≥3 beds available on MMHU — yes →

no

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As the trial progressed, pressures on acute medical bed availability increased, threatening recruitment rates. Two Norovirus outbreaks closed the MMHU for a total of four weeks; subsequent re-opening also disrupted allocations and recruitment. Figure 4 shows a graph of cumulative weekly recruitment per week during the trial.

Figure 4 Graph of Cumulative Recruited Patients per Week.
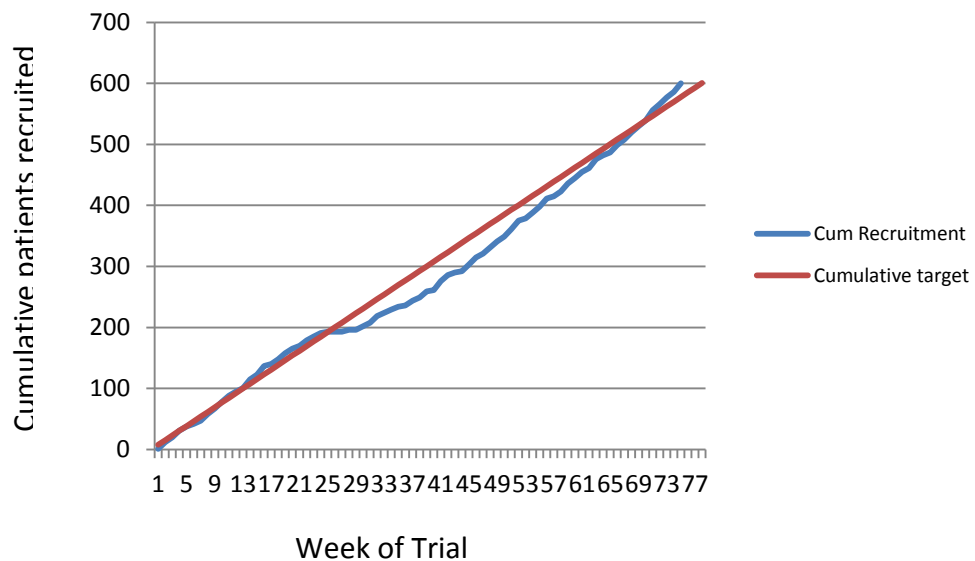
During the study, the algorithm was modified to ensure sufficient referrals to meet recruitment targets. Initially the algorithm was changed to randomise patients referred between midnight and 7am. Then, later in the trial patients resident at two postcodes initially not randomised were randomised (NG15 and NG16; both largely but not exclusively within the Nottingham PCT area). Towards the end of the trial, the number of empty beds above which patients were admitted without randomisation was increased firstly to 6, and finally all patients were randomised irrespective of MMHU's bed state. Whenever a change was made to the algorithm, prior to the change going live, it was thoroughly tested on a dummy site to ensure the change allocated patients correctly.

Patients readmitted to hospital following index admission were automatically accommodated according to their original allocation, if re-referred by the

Acute Medical Admissions Unit. Research nurses actively liaised with AMU ward managers and bed managers during the working day. Out-of-hours a senior clinician (consultant) investigator was on-call to deal with bed management problems. In practice, this algorithm randomised sufficient patients to recruit the target of between 8 and 10 participants per week, whilst remaining acceptable to hospital managers.

4.2.8. Recruitment and Consent for the NIHR TEAM trial

As soon as possible following ward allocation, research staff identified patients who had been randomised. This was usually within 24 hours, other than after a weekend when it could be up to 72 hours (for those randomised on Friday evening). After introduction to the researcher, the patient was assessed for mental capacity to give or withhold consent for participation in the study. This meant understanding, retention, reasoning and communication ability sufficient to decide on participating in a study collecting baseline and follow up data, and recording use of health and social care resources. This assessment was done by discussion, using a printed information sheet, supplemented by a simple and short summary, and a checklist of requirements set out in the Mental Capacity Act 2005 [267]. A hearing device was used if patients' had an auditory impairment.

Those having capacity were invited to give written consent to participation. Permission was asked to approach a family member or carer. The family member or carer was also given an information sheet and asked to give consent for their own involvement in the study. Most patients lacked capacity. The procedures set out in Section 32 of the Mental Capacity Act were then followed. A family member or carer was asked to act as a 'personal consultee', and asked if they had any reason to believe the patient would not have wanted to take part. If willing, they signed a consultee agreement form. If there was no contactable carer or if the carers could not visit the hospital (usually due to not living locally) and agreed verbally, the nurse in charge of the ward was asked to act as a 'professional consultee'

under section 32 (5) of the Mental Capacity Act. If he or she knew no reason why the patient would not want to participate, the patient was included. In this case, background data was, where possible, collected from care homes or from community care staff. The patient information sheet (short and long version) can be found in Appendix 8 and Appendix 9. Patients not recruited into the study continued with usual care on the MMHU, or standard care ward, and had no further contact with research staff.

4.2.9. Baseline Measurements

Data collection was by interview with a trained researcher. These were either registered nurses or psychology graduates. Information was collected from the patient participant and if possible, corroborated by a carer, or taken from family members or carers as informants. Where patients had auditory or visual impairments an amplification device (external hearing aid) and/or large print versions of questions were used. Carers were invited to complete a self-completion questionnaire, or were interviewed to complete the same information, if they preferred. Medical and nursing notes were scrutinised for diagnostic, drug and functional information. The baseline patient data collection form and the carer questionnaire are in Appendix 10 and Appendix 11.

Baseline data include:

- Social and demographic information, including age, sex, marital status, co-residence and type of accommodation.

- Cognitive impairment (Mini-Mental State Examination [268])

This is a widely used standardised measure of cognition. The MMSE tests orientation, registration, attention and calculation, recall, construction and language. It is scored out of 30, higher scores represent less impairment.

- Delirium diagnosis and severity (Delirium Rating Scale [269])

DRS-R-98, a 16-item clinician-rated scale with 13 severity items (sleep disturbance, hallucinations, delusions, lability, language, thought processes, motor agitation, motor retardation, orientation, attention, short term memory, long term memory, visual-spacial abilities) and three diagnostic items (temporal onset of symptoms, symptom fluctuation, physical disorder). It is scored out of 46, with delirium likely with a score over 17.75. Carers and staff were asked about the symptoms of the patient during the admission and up to three days prior to the admission.

- Physical disability (Barthel Index [270])

The Barthel Index consists of ten items that measure a person's daily functioning, specifically activities of daily living and mobility. The items include feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on a level surface, going up and down stairs, dressing, continence of bowels and bladder. Data was collected from hospital notes and staff at the time of recruitment. It is scored out of 20. Higher scores represent less disability.

- Behavioural and psychological symptoms (Neuropsychiatric Inventory (NPI), [271])

The NPI is a retrospective (up to one month) caregiver-informant interview covering 12 neuropsychiatric symptom domains: delusions, hallucinations, agitation/aggression, dysphoria/depression, anxiety, euphoria/elation, apathy/indifference, disinhibition, irritability/lability, aberrant motor behaviours, night time behavioural disturbances, and appetite/eating disturbances. It is scored out of 144, higher scores represent worse symptoms.

- Medical diagnoses.

- Illness severity (Modified Early Warning Score [272])

The Modified Early Warning Score (MEWS) is a simple guide used by hospital nursing & medical staff to quickly determine patients at risk of deterioration. It was based on data derived from physiological readings (systolic blood pressure, heart rate, respiratory rate, body temperature, urine output) and one observation (level of consciousness). Data on the MEWS was recorded from the medical notes on the day of admission. It is scored out of 21. Higher scores represent more severe acute illness.

4.2.10. Outcome Data

Carers were contacted by telephone to complete a satisfaction with care questionnaire between one and three weeks after the patient's discharge; other outcomes were ascertained by interview 90 days after randomisation. Resource use was collected by questionnaire and from electronic service records. This study only reports patient baseline data from the NIHR TEAM trial. Patient health status, carer data and resource use outcome data from the NIHR TEAM trial was not part of this thesis and will be analysed and reported separately.

4.2.11. Measures to Avoid Bias

Researchers were aware of the potential problems with the research design and the potential for bias due to differential non-recruitment. They were trained to adopt a rigorous approach to recruitment, whilst respecting an individual's right not to be involved in research if they so chose, or if circumstances (such as end of life care) made it inappropriate. Research staff operated shifts to be available when family carers were visiting. A contact log was maintained. The proportion of randomised patients recruited in each setting was monitored closely.

Training of Researchers

A large group of researchers worked on the NIHR TEAM trial. In addition to the researchers employed by the University of Nottingham, the NIHR TEAM trial was supported by the Mental Health Research Network, Trent Dementias

& Neurodegenerative Diseases Research Network, Trent Clinical Research Network and Nottingham University Hospitals NHS Trust. The number of researchers varied during the trial from seven to ten.

Such a large group of researchers presented the risk of observer error [273]. To mitigate against this risk a training programme was developed. All researchers completed Good Clinical Practice training prior to commencement of the trial. Two in house training sessions were organised to discuss key issues with the study and completion of the data collection forms. On the job training was provided which consisted of new researchers co-observing the recruitment process and interview with an experienced researcher. When confident, the new researcher recruited patients and interviewed the patient and carers under the supervision of an experienced researcher. This period of training lasted two to six weeks. All researchers recruited a patient and completed baseline data with the project manager (or later in the trial, an experienced researcher) observing them to ensure all questions were asked correctly (specifically with regard to time periods when observed behaviours happened) and data collected accurately. Where the researchers did not meet the expected standard, additional training was given on areas of weakness and the process repeated. Laminated checklists and guidance notes were given to all the researchers to aid accurate data collection. Researchers were encouraged to discuss concerns or uncertainties with the experienced researchers. The experienced researchers would either clarify how the data should be coded or if necessary, go and observe the patient in question. Where concerns were widespread how to collect data was clarified with the group of researchers or if necessary, additional training was given.

4.2.12. Sub-sampling for Observation

Participants to be observed were randomly sub-sampled from the patient participants randomised to the NIHR TEAM trial.

Random sampling was carried out by the University of Nottingham's Clinical Trials Unit.   The NIHR TEAM trial study number (a unique number assigned when the patient was randomised) for patients sub-sampled was sent to the researchers by email (see Appendix 3 for example). Initially, an ordered list of five patients were sub-sampled from the intervention arm (MMHU) and five from the control arm (standard care). The email was generated on Monday mornings and sub-sampling was from the previous week's randomisations (Monday to Sunday).   Two months into the trial, this was increased to eight patients being sub-sampled in each arm as a sub-sample of five patients did not always give the researchers anyone to observe. Recruitment to the NIHR TEAM trial was closely monitored to ensure all 88 observations could be completed before the end of the recruitment period. After a few months of observations a second subsample was requested. This was generated on a Thursday and was from randomisations from the previous Thursday to Wednesday. Observations from the Thursday sub-sample list were strictly alternated between MMHU and standard care wards to allow three observations to be done a week. For the last four weeks of the study four observations (two from Monday's and two from Thursday's sub-sample) were done due to the expected imminent completion of recruitment to the NIHR TEAM trial.

The first patient available on the list was observed, unless:

1. The patient had not been recruited to the NIHR TEAM trial. Reasons for this were:
    a. The patient declined to take part in the trial.
    b. The patient's carer declined consultee agreement for the patient to take part in the trial.
    c. The patient was too ill to approach to recruit. This was defined as being on the Liverpool (end of life) Care Pathway; where patients were ill, but not on the pathway they were revisited a few days later to see if they were suitable to approach. If they remained very ill, but not on the Liverpool Care Pathway, clinicians on the ward were asked if it was

appropriate to approach the patient's family. If recruited, and still in hospital the patient was observed, even if very ill.

    d. The patient was discharged before the researcher could recruit them.

    e. The patient died before the researcher could recruit them.

    f. The patient was already in a different NIHR Medical Crises in Older People trial (the AMIGOS trial [274], and consequently not recruited to the NIHR TEAM trial.

    g. The patient did not speak English and there was no family member to act as an interpreter.

    h. The patient had been randomised to one arm of the trial, but ended up in the other arm.

2. The patient was in a side-room (following advice from Bradford Dementia Group and an experienced ethnographic researcher it was decided observing patients in side rooms would be too intrusive).

3. The patient was discharged before the observation could be arranged (observations were prioritised where discharge was planned within 48 hours).

4. The patient, or another patient in the bay being observed objected to the observation (this never happened).

5. A member of staff objected to the observation (this never happened).

6. The patient had already been observed on a previous occasion (due to the overlap of dates on the two lists of sub-sampled patients produced each week).

7. If the patient was not recruited within seven days of randomisation, the next patient on the list was observed.

4.2.13. Consent to Make Observations

Written consent for the observational study was obtained at the time of recruitment to the NIHR TEAM trial, thereby avoiding a second consenting process. However, agreement to participate in research is an on-going process and it was important to confirm that the person with cognitive impairments agreed to continue with research irrespective of the consent in

place [275]. A form of 'process consent' [276] was used in this study and, irrespective of patients' mental capacity at the time of recruitment, verbal agreement to undertake the observations was sought prior to the period of observation from both the patient being directly observed and co-patients on the same hospital bay. In the event, no patients objected to the study.

The hospital ward is an open environment. It was not possible to obtain informed consent from all members of staff and other people on the ward who might be present during the observations. Staff on wards were briefed about the observations both during the pilot phase, during the handover on the day of the observation for early observations and on an individual basis to staff working on the bay for late observations. Notices were put up outside and on the ward notifying staff and visitors that an observation was being done, with photographs of the researchers. The researchers dealt with concerns of staff and visitors as they arose (no staff or visitors objected to the study, although many were interested in the study). This approach was discussed with the Nottingham NHS Research Ethics Committee and ethical approval was given on 16 March 2010.

4.2.14. Coding of Observations

During the six hour observation, every five minutes, a code was allocated to the patient based on the activity of the patient (one of 23 behaviour category codes, Table 3) and the researcher's perception of the patient's mood or engagement (one of six mood and engagement score, Table 4, page 90). Descriptions of the codes and the rules to follow when coding came from the Bradford Dementia Group, Dementia Care Mapping Manual [233].

4.2.14.1.   Behaviour Category Codes

Table 3: Behaviour Category Codes

Code	Description	Common Behaviours
A	Articulate	Holding a verbal exchange or speaking with another

		person. It could be either sustained talking or a brief exchange. It included non-verbal communication such as nodding, waving, smiling, making eye contact, physical touch.
B	Borderline	Sitting and observing or watching but not actively engaged with what was going on.
C	Cool	Being totally uninvolved and disengaged from the environment.
D	Doing for self	Engaging in independent activity related to self care such as putting on clothes, tying shoe laces, combing hair, tidying or straightening clothes, cleaning glasses, looking at self in mirror, smoothing hair, applying make-up, filing, cleaning or painting own nails, blowing or wiping own nose, washing hands or face, independently taking medication or tablets, scratching, nose picking.
E	Expressive	Engaging in activities that had a clearly creative or expressive element such as dancing, singing, art work, drama and engagement with music, playing musical instruments.
F	Food	Eating or drinking either independently or with assistance.
G	Going back	All types of reminiscence and life-review activities including structured reminiscence groups, handling objects to reminisce such as personal possessions, telling stories or recalling information about one's life, looking at pictures, books or magazines that evoked person memories, looking at photographs of family or places from one's past.
I	Intellect	An activity which prioritises the use of cognitive abilities such as memory, thought, recognition or reasoning. These include completing crosswords and other puzzles, quizzes, calculations, writing, playing scrabble or word games counting money and doing mental tests.
J	Joints	A game or activity where the primary focus is exercise or sport.
K	Kum and Go	Walking, standing or moving independently in a wheelchair.

L	Leisure	Looking at books, magazines or newspapers, playing board games, card games, watching television.
N	Nod, land of	Sleeping
O	Objects	Patients displaying attachment to or relating to objects such as toys, handbags, cutlery. It includes manipulation of or holding of objects.
P	Personal Care	Receiving practical or physical care including being washed, being dressed, changing dressings, assistance getting in and out of chairs or bed, eye care, being pushed in a wheel chair, being helped after vomiting or choking, being given medication, physiotherapy, physical examinations, manicures,
R	Religion	Religious activity.
S	Sexual	Expression that is clearly of a sexual nature.
T	Timalation	An activity which engages the senses including massage, aromatherapy, light displays.
U	Un-responded to	Calling out, asking questions, reaching out, crying, groaning, signing, shouting and grimacing.
V	Vocational	Work or work like activity including pseudo-work. Putting things straight, dusting, washing dishes, watering plants, housework.
W	Withstanding	Repetitive actions which are specifically about stimulating self including rocking, rubbing, wringing or twisting hands.
X	Excretion	Any action related to excretion. Includes asking for the toilet, walking to the toilet, using the toilet.
Y	Yourself	Interacting with yourself or an imaginary person. Includes hallucinations.
Z	None of the above codes	This category is used if behaviours do not fit into any of the above.

Where more than one behaviour category code occurred in a five minute time period, coding was decided by following a set of operational rules specified in the Dementia Care Mapping manual [233].

4.2.14.2.   Mood and Engagement Scores

Mood and engagement scores are always coded in the context of the behaviour category code that they accompany. The rules for coding behaviour category codes are followed before allocating the appropriate mood and engagement score.

Table 4: Mood and Engagement Scores

Mood	Score	Engagement
Very happy, cheerful. Very high positive mood.	+5	Very absorbed, deeply engrossed.
Content, happy relaxed. Considerable positive mood.	+3	Concentrating but distractible. Considerable engagement
Neutral. Absence of overt signs of positive or negative mood.	+1	Alert and focused on surroundings. Brief or intermittent engagement.
Small signs of negative mood.	-1	Withdrawn and out of contact.
Considerable signs of negative mood.	-3	
Very distressed. Very great signs of negative mood.	-5	

4.2.14.3.   Enhancers and Detractors

Extensive field notes were taken during the observation, relating to each 5 minute period. All interactions between staff (Nottingham University Hospitals and social services), students, agency workers and the patient being observed were recorded in the field notes. Within 24 hours of the observation, these were coded by the researcher by type of Personal Enhancers and Personal Detractors. Personal enhancers were staff behaviours that met the psychological needs of the patient and were thus likely to improve the patient's experience of care. Personal detractors were

staff behaviours that disregarded the psychological needs of the patient and were thus likely to diminish the patient's experience of care. Personal enhancers and personal detractors were coded into five categories: comfort (warmth, holding, relaxed pace versus intimidation, withholding, outpacing), identity (respect, acceptance, celebration versus infantilisation, labelling, disparagement), attachment (acknowledgement, genuineness, validation versus accusation, treachery, invalidation), occupation (empowerment, facilitation, enabling collaboration versus disempowerment, imposition, disruption, objectification), inclusion (recognition, including, belonging, fun versus stigmatisation, ignoring, banishment, mockery). Table 5 and Table 6 describe in more detail personal enhancers and personal detractors.

The purpose of this thesis was to determine if there were measurable differences in the quality of patients' experiences and care, using a randomised controlled trial to do so. The field notes were written to support the coding of the enhancers and detractors. In themselves, they were unsuitable and not intended for the purpose of measuring differences in the quality of experience.

Table 5: Description of Personal Enhancers

Enhancer	Title	Example
1	Warmth	Demonstrating genuine affection, care or concern for the participant.
2	Holding	Providing safety, security and comfort to a participant.
3	Relaxed Pace	Recognising the importance of helping create a relaxed atmosphere.
4	Respect	Treating the participant as a valued member of society and recognising their experience and age.
5	Acceptance	Entering into a relationship based on an attitude of acceptance or positive regard for the participant.

6	Celebration	Recognising, supporting and taking delight in the skills and achievements of the participant.
7	Acknowledgement	Recognising, accepting and supporting the participant as unique and valuing time as an individual.
8	Genuineness	Being honest and open with the participant in a way that is sensitive to their needs and feelings.
9	Validation	Recognising and supporting the reality of the participant. Sensitivity to feeling and emotion take priority.
10	Empowerment	Letting go of control and assisting the participants to discover or employ abilities and skills.
11	Facilitation	Assessing level of support required and providing it.
12	Enabling	Recognising and encouraging a participant's level of engagement within a frame of reference.
13	Collaboration	Treating the participant as a full and equal partner in what is happening, consulting and working with them.
14	Recognition	Meeting the participant in his or her own uniqueness, bringing an open and unprejudiced attitude.
15	Including	Enabling and encouraging the participant to be and feel included, physically and psychologically.
16	Belonging	Providing a sense of acceptance in a particular setting regardless of abilities and disabilities.
17	Fun	Accessing a free, creative way of being and using and responding to the use of fun and humour.

Table 6: Description of Personal Detractors

Detractor	Title	Example
1	Intimidation	Making a participant frightened or fearful by using spoken threats or physical power.
2	Withholding	Refusing to give asked for attention, or to meet an evident need for contact.
3	Outpacing	Providing information and presenting choices at a rate too fast for a participant to understand.
4	Infantilisation	Treating a participant in a patronising way as if they were a small child.
5	Labelling	Using a label as the main way to describe or relate to a participant.
6	Disparagement	Telling a participant that they are incompetent, useless, worthless, or incapable.
7	Accusation	Blaming the participant for things they have done, or have not been able to do.
8	Treachery	Using trickery or deception to distract or manipulate a participant in order to make them do or not do something.
9	Invalidation	Failing to acknowledge the reality of a participant in a particular situation.
10	Disempowerment	Not allowing a participant to use the abilities that they do have.
11	Imposition	Forcing a participant to do something, overriding their own desires or wishes or denying them choice.
12	Disruption	Intruding in or interfering with something a participant is doing, or crudely breaking their 'frame of reference'.
13	Objectification	Treating a participant as if they were a lump of dead matter or an object.

14	Stigmatisation	Treating a participant as if they were a disease object, an alien or an outcast.
15	Ignoring	Carrying on (in conversation or action) in the presence of a participant as if they are not there.
16	Banishment	Sending the participant away, or excluding them; psychologically or physically
17	Mockery	Making fun of a participant, teasing, humiliating them and making jokes at their expense.

4.2.14.4.   Recording Observations

The researchers followed the Bradford Dementia Group's Dementia Care Mapping instruction [233] and recorded the observations on data collection sheets specifically developed for this study (see pilot period page 103). Participants were observed for 6 hours (7am–1.45pm or 1.45pm–8.30pm including a 15min and 30min break). Breaks aimed to avoid patient meals. There were three cycles of breaks which were rotated. Breaks were predetermined to prevent selection bias [277], where breaks were not taken in error, data collected during the allocated break was omitted from the analysis. Where four hours of observation were not completed for a patient (defined as four hours of either behaviour category codes or mood and engagement scores), those data were not used in the final analysis. Initially early and late observations were strictly alternated for consecutive observations on MMHU or standard care wards, however when the rate of observations was increased to three a week, this was practically unmanageable and observations were only roughly alternated dependent on other commitments of the researchers.

To allow greater understanding of the patient's experience additional structured data was collected.

4.2.14.5   Staffing Levels

1. For each observation, numbers of nursing staff and students on the ward and assigned to the bay were recorded.   Staff were recorded by type (senior nurse (ward manager or deputy), staff nurse, healthcare assistant, mental health nurse).

2. Numbers of patients on the ward that day were recorded together with number of beds on the ward. As patients were often admitted and discharged during the observation, the number of patients at the beginning of the observation were recorded.

3. Some staff worked less than a full shift (due to training courses or non-standard shift patterns). These were recorded if they worked for more than half the observation period.

4. Often senior nurses were assigned to office duties, but helped staff out on the ward, particularly in the mornings. If a nurse was supposed to be doing office work on the day of observation they were not recorded in the staffing levels for that observation. Similarly if senior staff were not able to go home, and were staying late to deliver care, they were not recorded. (but the additional staffing would be recorded in the minimum and maximum staff on the bay – see below).

4.2.14.6   Environment

1. The temperature on the bay was recorded at the end of the early observation or at the beginning of a late observation.

2. For every five minute coding period noise levels were recorded:
   a) Noise was recorded by the following categories: buzzers (bed call alarms), intravenous infusion pump alarms, bed alarms, blood pressure machine alarms, telephones, radio or compact disc players, patients shouting repetitively or disruptively vocalising and 'other' noise -this category included: doorbells, mobile ring tones, television, fire alarms, loud printers, loud floor polishers or any other electronic noise which was deemed irritating by the researcher.
   b) Noise was defined as a sound the researcher could hear.

c) The noise was recorded only once for each five minute time period it was heard in.

3. Every five minutes, staff and visitors present on the bay being observed were recorded.

   a) Minimum and maximum staff on the bay in a five minute time period were recorded. These included all hospital staff, students (nurses, doctors and allied health professionals) and social workers. Researchers and care home staff were recorded as visitors. NIHR TEAM trial researchers were asked not to interact with the patient being observed whilst the observation was on-going.

   Bays were connected to one another by a walkway. Many staff walked along the walkway past the bay. To determine when a member of staff was on the bay the following rules applied:

   i.   If the member of staff walked down the walkway past the bay without stopping they were not included.
   ii.   If a member of staff sat or stood in the walkway and looked into the bay, they were included.
   iii. If there was an alcove opposite the bay and staff were sitting in it, watching the bay, they were included as on the bay. If they were writing notes and not watching the bay they were not included.

   b) Minimum and maximum number of visitors on the bay, including researchers and care home staff.

   Occasionally it was difficult to distinguish the job of the member of staff, and some hospital staff were on the bay as a visitor. If the researcher did not have the opportunity to ask the person or see their identity badge the researcher gave an educated guess as to who they were based on their interactions with the patients. This happened rarely.

4. Numbers of social interactions were recorded between the patient and anyone else (excluding the researcher). A social interaction could include a smile, or a wave. The number of social interactions the patient had was recorded for each 5 minute period. If the patient was spoken to but did not respond, or if the patient spoke to someone and they did not respond it was still recorded as a social interaction.

5. Obnoxious odours were not recorded in a structured manner, but were noted in the field notes.

4.2.14.7 Antipsychotic Drugs

Antipsychotic drugs administered to the patient on the day of the observation and in the week before the observation were recorded from the medication chart.

4.2.15 Selection of days to observe

Selection of day to do the observation was as follows:

1. On Mondays and Thursdays when the CTU sub-sampling email was received the list of patients to observe was reviewed to identify patients recruited. The hospital ward was then contacted to establish whether they were still in hospital and their expected discharge date.
2. Observations were prioritised for patients soon to be discharged.
3. Where possible, observations were done on or after the 4th day of the patient's admission (where date of randomisation was day 1).
4. To keep to target recruitment, observations needed to be done as soon as possible after the 4th day of observation.
5. Other work commitments of the researchers such as meetings and training courses dictated when observations could be done.
6. Afternoon observations completed at 20:30, commitments of the researchers outside of work therefore dictated when they could be done.
7. Where two observations were possible on the same day, the researcher alternated MMHU with standard care and early and late observations.

8. No attempt was made to identify staffing levels, skill mix, or individual members of staff on any ward prior to the observation.

Whilst this represented a convenience selection which had the potential to introduce selection bias, the practical restrictions meant there was little or no choice in the day the observations were done.

4.2.16 Ethics

Observations of care of people with dementia on a hospital ward were likely to involve observations of patients in undignified situations or in distress. This study was discussed at the Nottingham Research Ethics Committee meeting. The ethics committee specifically required that no observations be done behind screens when personal care was being given or in bathrooms or toilets. They raised no other ethical considerations related to the patient. However, there were ethical considerations when observing patients with cognitive impairment, and particularly making observations of patients in significant degrees of distress. In addition to obtaining informed consent or consultee agreement for the patient being observed, all patients on the bay being observed were asked for agreement prior to the observation taking place. Study details given were tailored to the understanding of the patient. It was explained to the patients, as far as they could understand, that we would be writing down everything we saw and heard during the observation and that it was for a study of care of older people on a hospital ward. No patients expressed any concerns about the observations and those who expressed an opinion were positive about the study. Some patients were unable to communicate due to severe cognitive impairment. If a visitor was present they were asked if they thought the patient would object to being observed. However, where a visitor was not present, these patients were included in the study. On some occasions patients arrived on the ward during the observation; only very limited notes were recorded about these patients. Observations were not discontinued due to the patients being in distress or being in an undignified situation. However, it was at the discretion of the

researcher when to stop an observation, or when further clarification was required to continue with the observation. If during the observation a patient became distressed by the researcher the researcher would stop the observation. If it was at the beginning of the observation, an attempt would be made to resume it. If a co-patient on the bay asked not to be observed, then they were excluded from the observation and it was clarified that this was acceptable to them.

Researchers only intervened directly in care giving where the situation was potentially dangerous for a patient. This was the same approach as that of Davies [278] and was similar to the approach used by National Audit of Dementia observations on wards. The most likely scenario for the patient being in a potentially dangerous scenario was due to risk of falls. The researchers used their judgement about this, but if staff were on the bay and could see the patient, the researcher would not intervene as staff would be more knowledgeable about the patient than the researcher. If a patient directly asked the researcher for assistance, the researcher would go to them and would pass on the request to a member of staff. If the patient was in general distress, but not directly appealing to the researcher, the researcher would position themselves out of the direct line of view of the patient, but would not intervene. To do otherwise, for some observations, would have involved the researcher comforting a patient for long periods of time defeating the purpose of the observation. At the end of the observation or at a predetermined break if it was felt that a significant need had not been met, such as the patient wanting a drink, the need was communicated to staff. If there were safeguarding concerns they would be raised with a senior clinician on the study to decide the best course of action (this never happened).

Patients and staff often interacted with the researcher. The researchers would not interact with patients or staff, but if patients or staff spoke to the researchers, the researcher would respond. Comments made by staff and the researcher's responses were recorded in the field notes. Where the patient being observed spoke to the researcher, the mood and engagement scores

and behaviour category codes were omitted for that 5 minute period as required by the Dementia Care Mapping User Manual [233].

4.2.17 Inter-rater reliability

Hour long joint observations were conducted throughout the study. These were done at a convenient time for both researchers. Where possible, researchers sat apart for joint observations. Where space was limited or the researchers needed to sit in a particular position to get a good view of the patient, the researchers did not communicate about the observation during the hour. Following the joint observation coding was compared and differences discussed. One researcher was identified in advance as the primary observer, and observations were not changed due to coding differences identified during the joint observation. The purpose of the joint observations was to maintain (or improve) consistency of coding and to document the inter-rater reliability quantitatively.

4.2.18 Blinding of Researchers

This was of necessity an un-blinded study, introducing the risk of expectation bias. Expectation bias occurs in the absence of masking or blinding, when observers may err toward the expected outcome. This bias usually favours the treatment group [277]. This was a limitation of the study. However, the two researchers had no involvement in the development of the intervention or the clinical care of the patients and regular did joint observations to ensure reliability of coding throughout the study. Using Bradford Dementia Group Dementia Care Mappers may have reduced the risk of expectation bias, however this was not practicable as it was important to capture the whole of the patient's day (07:00-20:30) as a significant amount of care is given outside of office hours. It was unlikely that Dementia Care Mappers could be hired to do these hours. Bradford Dementia Group Dementia Care Mappers were also prohibitively expensive at £600 a day, hiring them was an expense deemed unjustified.. Irrespective of cost, there were problems hiring dementia care mappers. At the time of the study design, Dementia Care Mapping had a

surge in popularity related to a television program 'Can Gerry Robinson Fix Dementia Care Homes?' [279] which featured Dementia Care Mapping. Informal discussions with Bradford Dementia Group and the difficulty experienced organising a gold standard Dementia Care Mapper for benchmarking suggested Bradford Dementia Group had insufficient Dementia Care Mappers to meet demand. This study required a significant degree of flexibility to complete all the observations making it impossible for external Dementia Care Mappers to do them. There was also a concern that the quality of the field notes would not be sufficient. Informal discussion and sight of the Dementia Care Mapping observations done by Bradford Dementia Group for an ethnographic study of healthcare assistants in a mental health hospital [280] showed that the standard of field notes written by Bradford Dementia Group's Dementia Care Mappers could be extremely limited. In order to describe how the MMHU differed to standard care wards, it was necessary to generate detailed field notes [to be qualitatively analysed, but outside the scope of this thesis].

4.2.19 Outcome measures

The primary outcome for this study was the proportion of time the patient was in positive mood or engagement. This was calculated as the time spent in mood or engagement scores +1, +3 and +5 divided by the total number of time periods where a mood or engagement score was recorded. Sleep was coded as 0 (not a positive mood) as excess sleep in the day suggested that the patient was either under-stimulated, had experienced disturbed sleep overnight or had delirium.

Secondary outcomes measures were:

1. Proportion of time in an active state. This was defined as time spent in behaviour category codes A, D, E, F, G, I, J, K, L, O, P, R, S, T, V, X, Y, Z (see page 87 for description of behaviour category codes) divided by the total number of time periods where a behaviour category code was recorded.

2. Number of personal enhancers occurring during an observation.

3. Number of personal detractors occurring during an observation.

4.2.19 Sample Size

The sample size for this study was 88 participants (44 from the MMHU and 44 from standard care wards). The main factor affecting sample size was feasibility (Dementia Care Mapping is very labour intensive). Informal advice from other researchers in the field doing observational studies of six or more hours considered doing one observation a week was feasible. Similar sample sizes of other observational studies had given statistically significant results [246, 281].

There was no information available in the published literature on the distribution of Dementia Care Mapping data to allow a power or precision-based sample size calculation. Attempts to obtain information on distribution of data from researchers who had done Dementia Care Mapping on acute hospital wards elsewhere were unsuccessful. The initial sample size calculation was therefore done on limited information. A Medical Crises in Older People statistician (Sarah Lewis) calculated using, NQuery software, that with 44 patients in each group, there was 80% power to detect a difference between groups with a 0.32 probability of an observation in one group being less than an observation in the other group (based on using a Mann Whitney U test).

The pilot period (see section 4.2.20) gave data on the distribution of mood and engagement scores and allowed more meaning to be placed on the original sample size calculation (such as what a 0.32 probability of an observation in one group being less than an observation in the other group would look like). Lucy Bradshaw (Medical Crises in Older People statistician) calculated that this sample size would have sufficient power to detect a clinically significant 11% difference between MMHU and standard care wards in proportion of time spent in positive mood and engagement or 90% power

to detect a difference in means of 12% using a two-sided independent t-test. A simulation exercise was conducted to examine how robust the power calculations for the study were to deviations from the normal distribution. The full sample size calculation is in Appendix 5.

4.2.20 The Pilot Period

Both researchers had direct clinical experience of the hospital care of people with mental health problems, and patients with severe behavioural problems. One researcher (SG) had worked as a nurse on a healthcare of the older person ward; the other (KW) as a healthcare assistant on an adult psychiatric ward. In November 2009 both researchers completed and passed an accredited three day Dementia Care Mapping basic user course including a written examination.

The pilot period was necessary to ensure both researchers were coding consistently and to mitigate against observation error [273]. The pilot period lasted from November 2010 to March 2011. During this time both researchers attended and passed the accredited four day Dementia Care Mapping- Advanced User course which included submission of a six hour Dementia Care Mapping observation which was checked for coding accuracy by the trainers, a written exam and an assessed report based on the 6 hour observation. Data collection sheets were developed, tested and refined (see Appendix 4). The two researchers made Dementia Care Mapping observations individually and then jointly. Following joint observations, coding was compared for consistency. There was initially a significant inconsistency between how the two researchers coded. After each observation, differences were discussed and resolved using the Bradford Dementia Group Dementia Care Mapping Manual [233]. A 'gold standard' Dementia Care Mapper from Bradford Dementia Group came to Nottingham University Hospital and spent three days doing joint observations with the researchers and discussing ways of ensuring consistency of coding. All observations were made on MMHU. By the end of this period the researchers

had achieved an 80% inter-rater reliability with the gold standard mapper on mood and engagement scores and behavioural category codes. Personal enhancers and personal detractors were discussed at length, but the inter-rater reliability was not calculated on these due to their relative infrequency. Following the sessions with the gold standard mapper, joint observations were resumed and kappa scores calculated. Observations were done on MMHU and standard care wards on patients who had been recruited to the NIHR TEAM trial. Dementia Care Mapping data from the early pilot period was used to perform a sample size calculation (see section 4.2.19).

Dementia Care Mapping was developed for use in day centres. It is extensively used in care homes and mental health wards. The acute hospital environment presented many challenges including the lack of space, privacy and a fast pace of activity. Some patients on the wards were acutely ill, some dying and others medically well and awaiting a care home placement. There had been only limited use of Dementia Care Mapping in such an environment. The gold standard mapper had no experience of Dementia Care Mapping on a hospital ward and was naive to research methods. The period of joint observations and the sessions with the gold standard mapper demonstrated that it was possible to get a good inter-rater reliability for mood and engagement scores and behavioural category codes, but much harder for personal enhancers and detractors.   The gold standard mapper was not further available until after the study needed to start. It was necessary to set a baseline of acceptable care in the hospital environment to decide when staff interactions were enhancing or detracting. It was felt important that the quality of staff interactions were recorded as a measure of process of care and as a proxy measure of patient experience.

The pilot period identified some commonly occurring situations and these were discussed with a group of clinicians, academics in the field and Bradford Dementia Group. Following these discussions a set of rules were developed. For other situations, the researchers based their decision on guidance in the Dementia Care Mapping manual, their training in Dementia Care Mapping

and advice given by the gold standard mapper. Specific examples of rules are

in Table 7, page 105.

Table 7: Rules of Scoring Detractors

Rules for Scoring Detractors		
Ignoring	Problem	How close does the staff member needed to be to the patient to be ignoring the patient
	Rule	The patient had to be acknowledged in some way if the staff member came within the area around their bed that could be screened. Acknowledgement of the patient's presence could be a smile or a nod or a brief word.
	Exceptions	If the patient appeared asleep or was highly focussed on a task and not obviously aware of the staff member, it was not a detractor if the staff member did not acknowledge them.
	Reasoning	The wards are very busy places; it is unrealistic to expect all staff to acknowledge all patients every time they walk onto a bay.
Infantilisation	Problem	Are the use of colloquial endearments such as 'love' and 'duck' acceptable?
	Rule	The staff member must initially use the patient's name, but subsequent terms such as love and duck would not give rise to a detractor.
	Exceptions	Unless the patient appears to object to these terms or they are used in a patronising way.
	Reasoning	These terms are regularly used around Nottingham and are used by patients to nurses frequently. They are often used in a caring way and patients do not obviously object to them. Paul Vallely in 'The Independent' [282] made a similar point about regional differences in whether such terms are acceptable.
Disruption	Problem	Is it a detractor for phlebotomists to do venepuncture or a nurse to give eye drops without closing the screen.
	Rule	This will be regarded as a neutral interaction.
	Exceptions	Unless the patient requests more privacy or seems to be concerned about the lack of privacy. If clothes need to be removed to deliver the care (other than cardigans or dressing gowns),

		then not drawing the screens is a detractor.
	Reasoning	Whether desirable or not, this is standard behaviour on all wards. Clinical advice and the experience of the researchers suggested that patients often do not like screens being drawn around them. There are other situations (such as when donating blood) where such procedures are done in a public environment.
Invalidation	Problem	Many patients are hard of hearing and personal questions such as whether they need the toilet or the state of their bowels are asked at a loud volume
	Rule	If the staff member makes an attempt to ask the question discretely, this is not a detractor. If they ask the question with no sensitivity to the personal nature of the question such as across a bed or from further away, this is a detractor.
	Exceptions	None
	Reasoning	There are no opportunities for private conversations in a hospital bay. Communication has to be done somehow.
Invalidation	Problem	Patient care discussed on the bay i.e. for doctors ward rounds or handover.
	Rule	If the staff member introduces themselves to the patient first and says they will be discussing the patient's care then this is neutral. The discussion then needs to be at a volume that the researchers cannot hear. Private conversations with the patient must be behind a screen, however, if the volume is at a level that the researcher can hear this will not be a detractor. Handover of care on the bay or at reception will be a detractor if the researchers can hear personal details.
	Exceptions	None
	Reasoning	The limitations of privacy on the ward are such that it is beyond staff control to make all conversations private.

In addition to this, there were times where an enhancing behaviour or detracting behaviour went on for many five minute time periods. For example giving comfort to a patient in distress for 30 minutes or ignoring a

patient in distress for 30 minutes. For these situations, an enhancer or detractor was given for each five minute time period the behaviour was seen in. If more than one detractor or enhancer was present alongside then these were recorded as well (but only once). It was decided that personal enhancers and detractors would not be categorised as highly enhancing or detracting (as detailed in the Dementia Care Mapping manual [233] as this would add another variable and would increase the risk of observer error.

As we were interested in staff behaviours we only recorded personal detractors and enhancers for Nottingham University Hospital staff or students and social services staff. Visitors (including care home staff and researchers) did not have their interactions coded, but could improve or diminish the mood or engagement or activity of the patient.

By the end of the pilot period, both researchers were immersed in the acute hospital ward environment, felt confident about Dementia Care Mapping, had completed 13 hours of joint observations, achieving an agreement in coding of: behaviour category codes 88%, kappa 0.86; mood and engagement scores 85%, kappa 0.74 and personal enhancers, personal detractors and neutral observations of 72%, kappa 0.49. The researchers' skills at doing the study were deemed sufficient to start the main study.

4.2.21 Data Handling

Data were collected on study specific data collection forms. All data were entered onto a Microsoft Access database. The database was built by a database technician under my instruction. The two researchers entered the data onto the database. Data were extensively checked to reduce the risk of data coding error [273]. Total numbers of mood and engagement scores, behaviour category codes, personal enhancers and detractors were collated on data checking forms and agreed to the summarised data available on the database reports. 100% of number and types of staff on the ward and on the bay being observed, temperature and antipsychotic drugs used as recorded on the raw data sheets were checked to the database. Every 10th record was

checked for noise levels, staffing and visitor numbers and social interactions. Low levels of errors were found and corrected (2% errors on noise, 1% error on minimum and maximum staff on the bay, 0.5% errors on minimum and maximum visitors on the bay and 0.6% error on social interactions). Many errors were categorisation errors rather than errors of omission or inaccurate inclusion. The levels of error were not deemed sufficient to make a material difference to interpretation of the results and no further data checks were considered necessary.

Data taken from the NIHR TEAM trial dataset (demographics, MMSE, DRS, NPI, Barthel, MEWS) was checked for accuracy by the NIHR TEAM trial researchers and a MNursSci undergraduate nurse. Data were checked for accuracy in a variety of ways. Data were double-entered (entered independently onto two databases and reports generated of differences). Items on these reports of data differences were investigated and the data corrected. Data comparison reports were generated after each round of data checks until no differences were identified. The comparison reports were initially checked to ensure they identified all data errors by entering and checking incorrect dummy data. The database technician created reports in the database to summarise the health status measurement instruments. 5% of patients' details were checked in detail to ensure they correctly reported the details recorded. A statistician created exception reports of unusual data and missing data and these were followed up to ensure all data collected had been entered onto the database. The researchers corrected the occasional other errors as they became apparent when doing the above checks.

4.2.22 Data Analysis

Where data were missing it was excluded from the analysis. If less than four hours of data was collected (patient being off ward or out of view for reasons other than personal care or toilet), the whole observation was excluded from the analysis. All statistical analysis was done using STATA version 11 software (Statacorp, College Station, TX)

General considerations

I performed all statistical analyses. To reduce the risk of calculation error [273] all the statistical analyses for baseline and outcome data were independently calculated by a statistician (Lucy Bradshaw). Results were compared and differences investigated until agreement was reached. The statistician performed her data analysis blind to ward allocation.

Simple statistics were used to summarise baseline data.

Prior to analysis the distribution of the data was checked and investigated to see if it could be transformed to a normal distribution.

1. Proportion of time in positive mood or engagement

   These data were negatively skewed. When the data were separated into ward allocation there was a different distribution of data for the two ward types. A logarithmic transformation transformed the overall data to a normal distribution. However, when the two ward types were looked at individually, the logarithmic transformation transformed the data of MMHU to normally distributed, but the data of standard care wards was negatively skewed. Discussions with the statistician concluded that a non-parametric test was the most appropriate for the data.

2. Proportion of time in active state

   This data was negatively skewed. No transformation could be identified which transformed it to parametric. A non-parametric test was therefore deemed the most appropriate.

3. Number of personal enhancers and personal detractors.

   This was ordered categorical data and a non-parametric test was necessary.

For the outcome data, bootstrapping techniques were used to calculate the 95% confidence intervals for the difference between the medians. Bootstrapping is a way of deriving confidence intervals where there is only limited information about the probability distribution that gave rise to the data. It involves taking a random sample from the original data, replacing it back in the dataset and then taking another random sample from the original data continuously until a new dataset of the same size as the original one is created. This is done separately for data of each ward type. The difference between the medians of the two new datasets is then calculated. This procedure is then repeated a minimum of one thousand times. The 95% confidence interval for the difference between the medians is then derived using the dataset of bootstrapped samples. The percentile method takes the range of the bootstrapping samples created from the 2.5[th] percentile to the 97.5[th] percentile of the distribution [273]. This method, whilst simple, is not always accurate as it assumes that the samples created by bootstrapping are normally distributed. All bootstrapping derived 95% confidence intervals derived from the percentile method were compared to another method, the bias corrected and accelerated (BCa) confidence intervals (which are corrected for bias and skewness in the bootstrap distribution [283, 284]) calculated by a Medical Crises in Older People Statistician – Lucy Bradshaw- and were found to be similar .

Pearson's product moment correlation was used to calculate the correlation coefficient to measure the strength of the linear association between the outcome variable of number of enhancers and number of detractors and the exposure variables of ratio of patients to numbers of nursing staff (including healthcare assistants and nursing students) working on the shift being observed.

4.2.23 Patient and Public Involvement

Development of the Study

This study was discussed with a number of carers of people with cognitive impairment who had recent experience of the general hospital. They were all enthusiastic that the research took place and considered the patient experience of care on a hospital ward to be one of the most important outcomes of the MMHU's evaluation.

Management of the Study

This study came under the management of the NIHR TEAM trial. A trial steering committee was formed to oversee the trial. Three lay consultants were members of the Trial Steering Committee.

Synthesis and Dissemination of Results

Further patient and public involvement was planned for synthesis and dissemination of the results of this study, but is outside the scope of this thesis.

4.3.   Conclusion

This pragmatic study design represented as close to a randomised controlled trial of cognitively impaired, older patients' experiences of care, as was possible in an NHS general hospital. The study design included consideration of, and decision on, how to randomise patients to the MMHU or standard care wards, the training and management of a large team of researchers, the ethics of recruiting and observing older people without capacity, the piloting of Dementia Care Mapping in the hospital and procedures put in place to minimise bias and error. The next section details the results of this study.

5. Analysis of the Data (Results)

This chapter gives details of the results of the structured, non-participant observational study. Results are given of patients sub-sampled, and reasons for not observing sampled patients, the inter-rater reliability between the two researchers, baseline statistics on who was observed, statistics on the environment in terms of noise and temperature, the numbers of nursing staff and students working on the shift being observed and the numbers of staff, students, volunteers and visitors on the bay being observed. Statistics are presented on the outcome measures of proportion of time in a positive mood and engagement, proportion of time in an active state, number of enhancers and number of detractors. Data are also presented on the individual behaviour category codes and mood and engagement scores. Correlations are presented between staffing levels and numbers of enhancers and detractors. Information is given on enhancers and detractors by type and by which staff delivered them.

5.1. Patients Observed

Over 10 months, between 7 March 2011 and 19 December 2011, 525 patients were randomised to the NIHR TEAM trial. From these patients 474 unique randomly sub-sampled patients were generated by the University of Nottingham Clinical Trials Unit (235 MMHU; 239 standard care wards). In total 90 observations were completed (46 on MMHU and 44 on standard care wards). More patients gave informed consent (or their carers gave consultee agreement) on MMHU than standard care wards (only 19 (19%) patients (or carers) declined to take part in the NIHR TEAM trial on MMHU compared to 28 (25%) patients on standard care wards). More patients were cared for in side rooms (preventing observation) on standard care wards than on MMHU (3 (3%) of patients were not observed due to accommodation in side-rooms on MMHU compared to 10 (9%) on standard care wards). Otherwise, reasons for not observing sub-sampled patients were similar between the two ward types. Figure 5 gives reasons why sub-sampled patients were not observed.

Figure 5: Consort diagram of patient observed
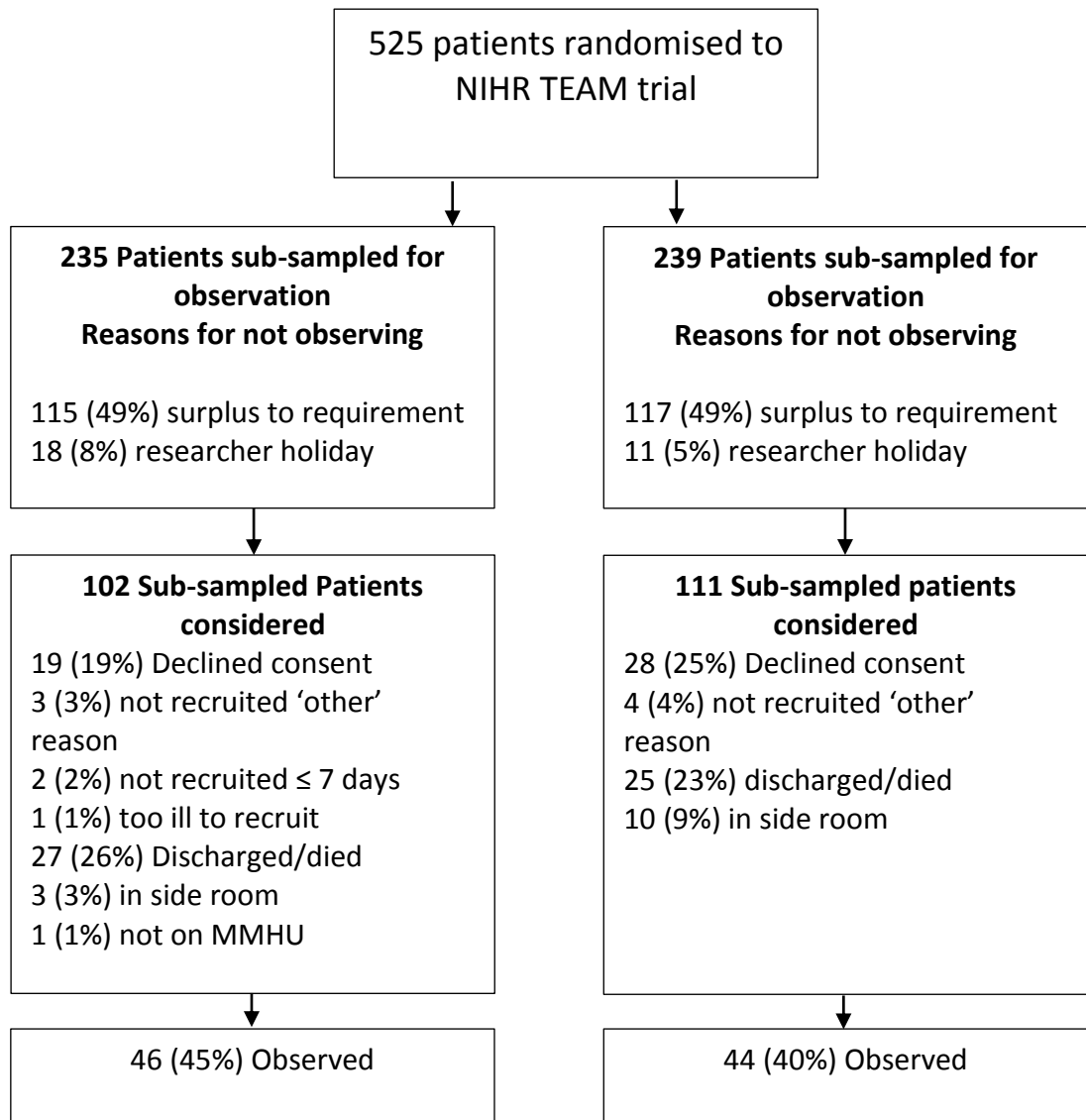
Those observed were similar to those patients randomised and not observed in terms of median age (84 years versus 85 years); female sex (51% versus 50%) and postcode residence.

Patients observed were similar to those recruited to the NIHR TEAM trial in terms of median age (85 versus 84), female sex (51% versus 51%), median MMSE (13 versus 14), median Barthel Index (7 versus 9) and median NPI total (22 versus 25).

Patients observed had stayed in hospital for a similar number of days on MMHU and standard care wards. The median (IQR) day that observations were conducted on MMHU was 6 (5-8) and for standard care wards 7 (5.5-8). There were similar numbers of missed five minute observations on MMHU and standard care wards (median (IQR) 2 (0-7) versus 3 (0-7.5))

Control observations (standard care wards) were done on five Healthcare of the Older Person wards (37/44, 84%), three acute medical wards (5/44, 11%) and two trauma-orthopaedic wards (2/44, 5%).

5.2. Inter-rater reliability

The two researchers completed 22 (11 MMHU; 11 standard care wards) joint one hour observations throughout the study (15 March 2011 to 2 December 2011). Percentage agreement between the two observers and kappa scores were calculated.

For behaviour category codes there was 88% agreement between the coding categories, kappa 0.85. For mood and engagement scores there was 78% agreement in coding, kappa 0.66. For personal enhancers, detractors and neutral interactions between patients and staff (or students) there was 72% agreement, kappa 0.5.

The ratio of observations on MMHU to standard care wards was the same for both researchers (51%/49% versus 51%/49%). Sarah Goldberg (SG) conducted 60% of the observations and Kathy Whittamore (KW) 40% of observations.

5.3. Baseline Data

5.3.1. Demographics

Median (IQR) age was 86 (81-88) years and 51% of patients observed were female. Patients observed were mostly white (98%). 52% lived alone; 30% lived with another; 18% lived in a care home. 26% of patients were married, 74% were widowed, divorced or single. Characteristics of MMHU and

standard care ward patients were similar for age, sex and ethnicity. However, more patients lived in care homes on MMHU than on standard care wards (24% versus 11%) and patients on MMHU were more likely to be married (30% versus 21%). Table 8 gives details of patient demographics.

Table 8: Patient Demographics

	MMHU	Standard Care Wards	Total	p
Age (years) Median (IQR)	86 (83-89)	86 (81-88)	86 (81-88)	**0.83**
Gender: Female	24/46 (52%)	22/44 (50%)	46/90 (51%)	**0.84**
Ethnicity: white	45/46 (98%)	43/44 (98%)	88/90 (98%)	**0.98**
Residence: Lives alone	20/46 (43%)	27/44 (61%)	47/90 (52%)	**0.31**
Lives with other	15/46 (33%)	12/44 (27%)	27/90 (30%)	
Lives in care home	11/46 (24%)	5/44 (11%)	16/90 (18%)	
Marital Status: Married	14/46 (30%)	9/43 (21%)	23/89 (26%)	**0.31**
Widowed, divorced or single	**32/46 (70%)**	**34/43 (79%)**	**66/89 (74%)**	

IQR= Interquartile range

5.3.2. Physical and Mental Health Characteristics

At baseline fewer MMHU patients had eyesight problems (MMHU 24% versus standard care wards 34%) and had fewer patients presenting with reduced mobility (MMHU 46% versus standard care wards 57%). Using the Barthel Index, standard care ward patients were more disabled (26% of MMHU patients versus 39% standard care ward patients had a Barthel Index score of 0-5). Cognitive function on MMSE was similar between groups and

was severely impaired (37% of patients had an MMSE of 10 or less). Patients on MMHU had greater behavioural and psychological disturbance at baseline (Median NPI of 28 on MMHU versus 19 on standard care wards). Other characteristics were similar between the two groups.

Table 9, page 117, gives details of patients' baseline characteristics.

Table 9: Baseline Patient Characteristics

	MMHU	Standard Care Ward	Total	p
MMSE Score 0-10	16/46 (35%)	17/43 (40%)	33/89 (37%)	0.42
11-20	24/46 (52%)	17/43 (40%)	41/89 (46%)	
21-30	6/46 (13%)	9/43 (21%)	15/89 (17%)	
NPI score median (IQR)	28 (13-39) n=32	19 (9-34) n=33	22 (12-37)	0.41
Barthel Index: 0-5	12/46 (26%)	17/44 (39%)	29/90 (32%)	0.60
6-10	18/46 (39%)	15/44 (34%)	33/90 (37%)	
11-15	8/46 (17%)	7/44 (16%)	15/90 (17%)	
16-20	8/46 (17%)	5/44 (11%)	13/90 (14%)	
Diagnosed dementia	27/46 (59%)	27/44 (61%)	54/90 (60%)	0.80
Delirium (DRS>17.75)	25/46 (54%)	23/44 (52%)	48/90 (53%)	0.84
MEWS 4 or more	5/45 (11%)	7/44 (16%)	12/89 (13%)	0.51
Antipsychotics in week prior to observation	7/46 (15%)	5/44 (11%)	12/90 (13%)	0.59
Consent no capacity	36/46 (78%)	31/44 (70%)	67/90 (74%)	0.40
Eyesight problems	11/46 (24%)	15/44 (34%)	26/90 (29%)	0.29
Hearing problems	10/46 (22%)	8/44 (18%)	18/90 (20%)	0.67
Presented with falls	24/46 (52%)	23/44 (52%)	47/90 (52%)	0.99
Reduced mobility	21/46 (46%)	25/44 (57%)	46/90 (51%)	0.29
Continence disorders	6/46 (13%)	5/44 (11%)	11/90 (12%)	0.93
Deteriorating cognitive skills	30/46 (65%)	27/44 (61%)	57/90 (63%)	0.70

MMSE Mini Mental State Examination, NPI Neuropsychiatric Inventory, DRS Delirium Rating Scale MEWS Modified Early Warning Score.

5.4. The Environment

5.4.1. Staffing, Visitors and Social Interactions

Qualified nursing staff on MMHU cared for 5.0 patients each compared to 6.4 on standard care wards (mean difference -1.5 (95%CI -2.1, -0.8); p<0.001) The nurses and healthcare assistants on MMHU together cared for 3.1 patients compared to 4.1 patients on standard care wards (Mean difference -1.0 (95%CI -1.3, -0.7); p<0.001). There were also more students on MMHU compared to standard care wards with students present during 76% of observations compared to 55% of observations on standard care wards (p=0.03). The ratio of registered to unregistered nurses was similar between the two wards (65%/35% versus 67%/33%). Table 10 gives details of the nurse staffing on the wards.

Table 10: Nursing Staff on the ward

	MMHU	Standard Care	Difference between mean/medians (95%CI)	p
Mean (sd) Patients/qualified nurse	5.0 (1.2)	6.4 (1.7)	-1.5 (-2.1, -0.8)	<0.001
Mean (sd) Patients per nurse or HCA	3.1 (0.6)	4.1 (0.7)	-1.0 (-1.3, -0.7)	<0.001
Observations with students on ward	35/46 (76%)	24/44 (55%)	n/a	0.03 (chi^2)
Median (IQR) students	1 (1-3)	1 (0-2)	0 (0, 2)	0.007
Ratio registered/unregistered	65%/35%	67%/33%	n/a	0.34

HCA=Healthcare Assistant, sd=standard deviation, IQR=Interquartile Range

Minimum and maximum number of all staff and students was recorded on the bay every five minutes. There was more time on standard care wards when there was no staff member (or student or volunteer) on the bay than on MMHU (17% versus 10%). The difference between the medians (MMHU versus standard care wards) was -7% (95%CI -10%, -1%); p=0.005. The median number of staff (or students) on the bay during any one five minute time period was also higher on MMHU (1.4) than standard care wards (1.1). The difference between the medians was 0.3 (95%CI 0.1, 0.6); p=0.003.

Visitors tended to visit only in the afternoons. The median proportion of time visitors were on the bay was higher on MMHU (38% versus 23%), although the upper quartile was higher for standard care wards (70% versus 60%) and for 25% of the time there were no visitors present. These differences were not statistically significant.

The total number of social interactions experienced by patients on MMHU was 40 compared to 32 on standard care wards (difference between the medians 8 (95%CI -4, 19); p=0.12). The proportion of observation periods that a social interaction took place was 47% on MMHU and 39% on standard care wards (difference between the medians 8% (95%CI -3%, 19%); p=0.06). These differences were not statistically significant.

Table 11 gives details of the staff and visitors on the bay being observed and the social interactions the patient had.

Table 11: Staff and Visitors on the Bay and Patient's Social Interactions

	MMHU Median (IQR)	Standard care Median (IQR)	Difference between medians (95%CI)	p
Average staff on bay	1.4 (1.2-1.7)	1.1 (1.0-1.5)	0.3 (0.1, 0.6)	0.003
Proportion of time no staff on bay	10% (4-17%)	17% (8-23%)	-7% (-10%, -1%)	0.005
Proportion of time visitors on bay	38% (0-60%)	23% (0-70%)	15% (-28%,44%)	0.83
Proportion of time a social interaction occurred	47 % (32%-60%)	39% (30%-51%)	8%(-3, 19%)	0.06
Number of social interactions	40 (26-53)	32 (26-46)	8 (-4, 19)	0.12

5.4.2. Noise and Temperature

Table 12 shows the temperature and noise during the observations. The temperature on all wards was consistent, but warm, at 25 degrees Celsius. Patients on MMHU experienced an overall lower noise level compared to standard care wards with a median difference in proportion of time overall noise could be heard of -13% (95%CI -17%, -7%; p<0.001) (MMHU 79% versus standard care wards 92%). Noise from alarms was lower on MMHU compared to standard care wards with the median difference in proportion of time alarms could be heard of -15% (95%CI -21%, -9%; p<0.001) and background noise -18% (95%CI -33%, -3%; p=0.003). Patients experienced more noise from other patients calling out repetitively or in distress on

MMHU than on standard care wards (21% versus 6%), with a difference between the medians of 15% (95%CI 1%, 23%; p=0.04).

Table 12: Noise and Temperature on the Ward

	MMHU Median (IQR)	Standard Care Median (IQR)	Difference Between Medians 95%(CI)	p
Temperature	25 (24-26)	25 (24-26)	n/a	n/a
Proportion time alarms	59% (49-65%)	74% (66-85%)	-15% (-21,-9%)	<0.001
Proportion time background noise	25% (15-36%)	43% (22-66%)	-18% (-33,-3%)	0.003
Proportion time co-patients call out	21% (4-40%)	6% (2-22%)	15% (1,23)	0.04
Proportion time any noise	79% (74-88%)	92% (81-96%)	-13% (-17,-7%)	<0.001

5.5. Outcomes

The breakdown of the proportion of time spent in different behaviour category codes can be seen in Table 13. Some behaviour category codes were rarely used, the table only shows the behaviour category codes where the median was greater than zero. There were no major differences between the two settings.

Table 13: Proportion of Time in Behaviour Category Codes

Activity Code	MMHU Median (IQR)	Standard Care Median (IQR)	Difference between medians (95%CI)	P
A (talking)	19% (11-28%)	15% (8-22%)	4% (-3%, 11%)	0.13
B (passive)	5% (2-9%)	8% (4-15%)	-3% (-7%, 0)	0.10
C (disengaged)	7% (3-10%)	8% (3-17%)	-1% (-6%, 2%)	0.20
D (doing for self)	12% (7-20%)	15% (7-24%)	-3% (-10, 3%)	0.30
F (food)	10% (7-15%)	12% (6-15%)	-1% (-4%, 2%)	0.85
K (walking)	1% (0-7%)	2% (0-6%)	0% (-3%, 4%)	0.83
N (sleeping)	2% (0-13%)	6% (0-16%)	-4% (-9%, 1%)	0.21
O (interacting with object)	1% (0-4%)	1% (0-3%)	0 (-2%, 2%)	0.71
P (personal care)	7% (3-10%)	7% (4-12%)	0 (-5%, 2%)	0.26
V (vocational activity)	2% (0-7%)	1% (0-5%)	0 (-1%, 3%)	0.25
X (toilet)	1% (0-3%)	2% (0-6%)	0 (-2%, 2%)	0.49

The breakdown of proportion of time spent in the different mood and engagement states can be seen in Table 14. Due to low numbers of +5 scores (there were five timeframes coded as +5 on MMHU versus zero on standard care wards) and -5 scores (there were eight timeframes coded as -5 on MMHU versus 5 on standard care wards), these have been included with the +3 and -3 scores. Categorising these scores together made no difference to the statistical significance of the results. There was a greater proportion of time spent in mood and engagement score of -1 (mildly negative) on standard care wards (median difference -9% (95%CI -13%, -2%; p=0.05))

Table 14: Proportion of Time in Mood and Engagement States

Mood and Engagement (proportion of time)	MMHU Median (IQR)	Standard Care Median (IQR)	Difference between medians (95% CI)	P
+3 or +5 (positively engaged or happy)	36% (17-57%)	29% (16-37%)	7% (-5, 18%)	0.20
+1 (neutral)	38% (18%-51%)	37% (32%-50%)	0 (-11, 12%)	0.5
Zero (asleep)	2% (0-13%)	6% (0-17%)	-5% (-9, 1%)	0.18
-1 (mildly negative mood or disengaged)	11% (8-21%)	20% (12-27%)	-9% (-13, -2%)	0.05
-3 or -5 (obvious signs of distress)	0 (0-2%)	0 (0-2%)	0 (0, 0)	0.98

5.5.1. Proportion of time in positive mood and engagement

Patients spent a greater median proportion of time in a positive mood and engagement on MMHU compared with standard care (79% versus 68%, median difference 11%, 95% CI 2%, 20%).
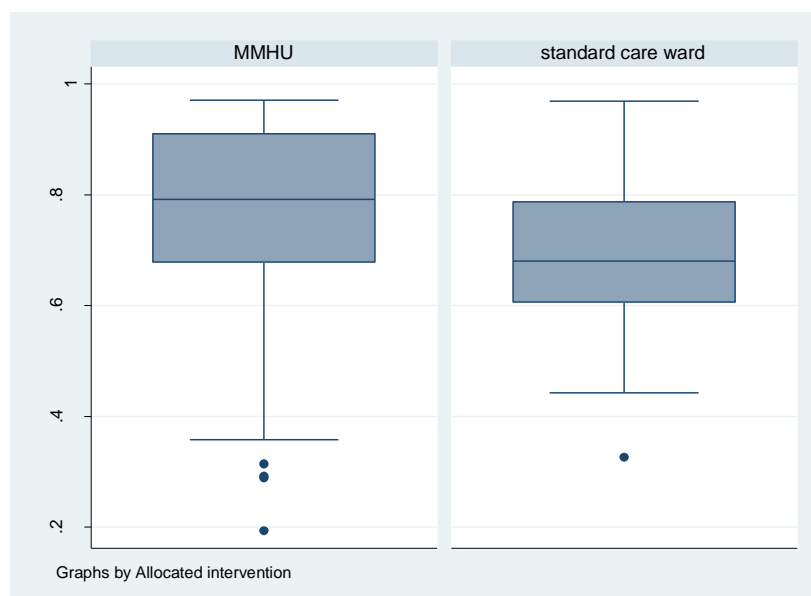
The probability that this difference could have occurred by chance was 0.03. The probability that a randomly selected patient from MMHU spends a higher percentage time in positive mood than a randomly selected patient on standard care was 0.63 (Table 15, Figure 6).

Table 15: Outcome Measures

	MMHU Median (IQR)	Standard Care Wards Median (IQR)	Difference Between the Medians (95% CI)	p
Proportion time in positive mood/engagement	79% (68-91%)	68% (61-79%)	11% (2, 20%)	0.03
Proportion time in active state	82% (69-92%)	74% (58-86%)	8% (-2, 16%)	0.10
Number of enhancers	4 (1-8)	1 (0-3)	3 (1, 5)	<0.001
Number of detractors	4 (2-7)	5.5 (3-10.5)	-1.5 (-4, 1)	0.08

Figure 6: Distribution of proportion of time in positive mood and engagement

Graphs by Allocated intervention

5.5.2. Proportion of time in active state

The median (IQR) proportion of time patients spent in an active state on MMHU was 82% (69%-92%) while on standard care wards it was 74% (58%-86%). The difference between these medians (95% CI) was 8% (-2%, 16%). The probability that this difference could have occurred by chance was p=0.10. The probability that a randomly selected patient from MMHU spent a higher percentage of time in an active state than a randomly selected patient from standard care was 0.60 (Table 15, Figure 7).

Figure 7: Distribution of Proportion of Time in an Active State

Graphs by Allocated intervention
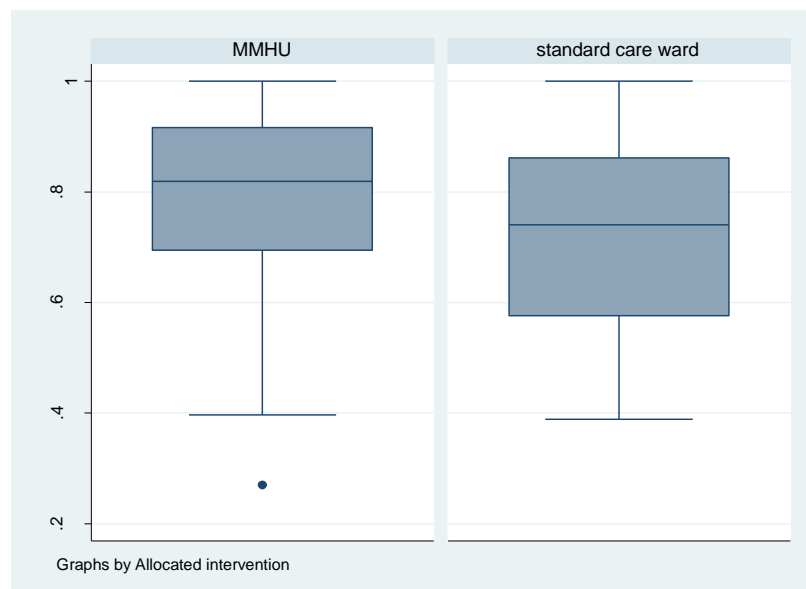
5.5.3. Number of enhancers and detractors

The median number of enhancers per observation was 4 (IQR 1-8) on MMHU and 1 (IQR 0-3) on standard care wards. The difference between the medians of these results was 3 (95%CI 1, 5).The probability that this difference could have occurred by chance was less than 0.001. The probability that a randomly selected patient from MMHU had a greater number of enhancers than a randomly selected patient from standard care was 0.74 (Table 15, Figure 8).

Figure 8: Distribution of Enhancers

Graphs by Allocated intervention
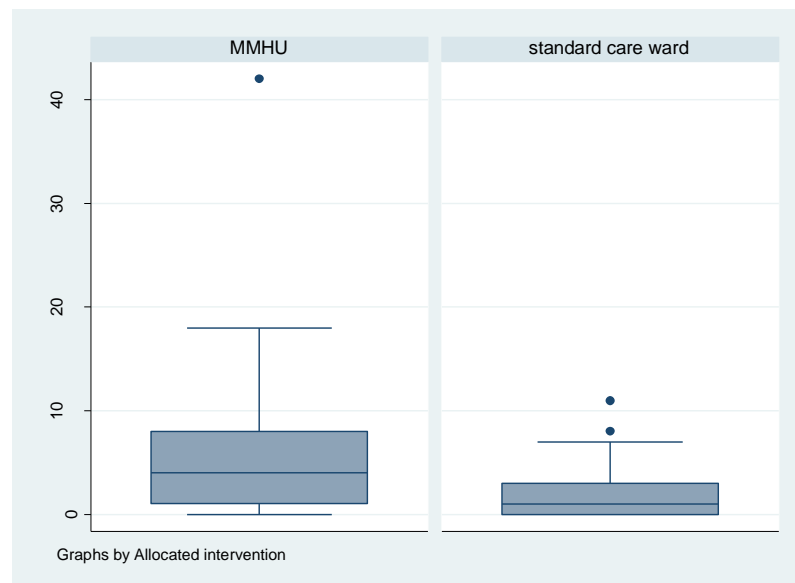
Personal enhancers were negatively correlated to the ratio of patients to nursing staff and students such that the greater the number of patients per nurse (healthcare assistant or student) on the day of the observation the fewer enhancers they received (r=-0.32, p=0.002) (Figure 9).

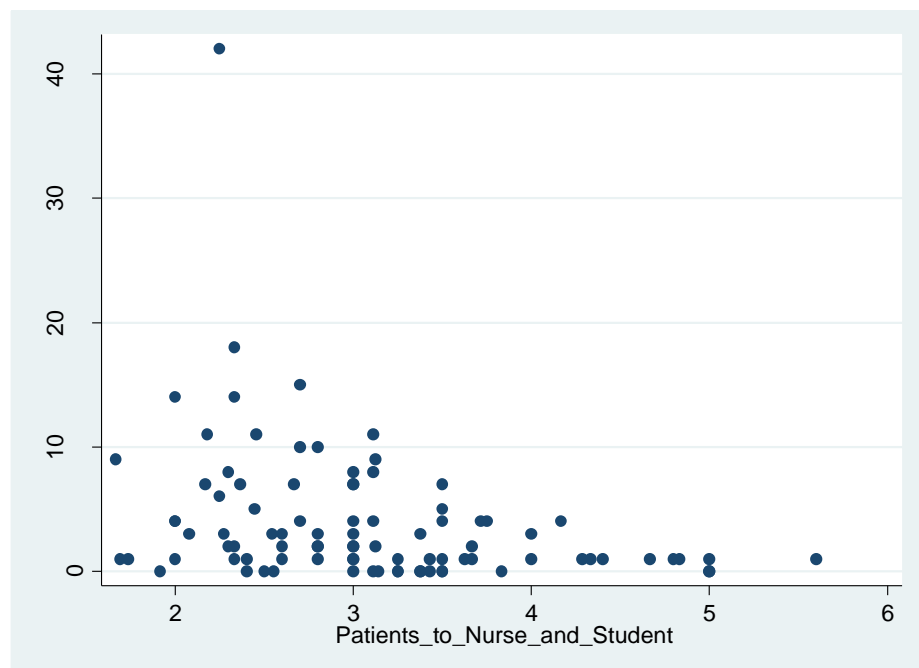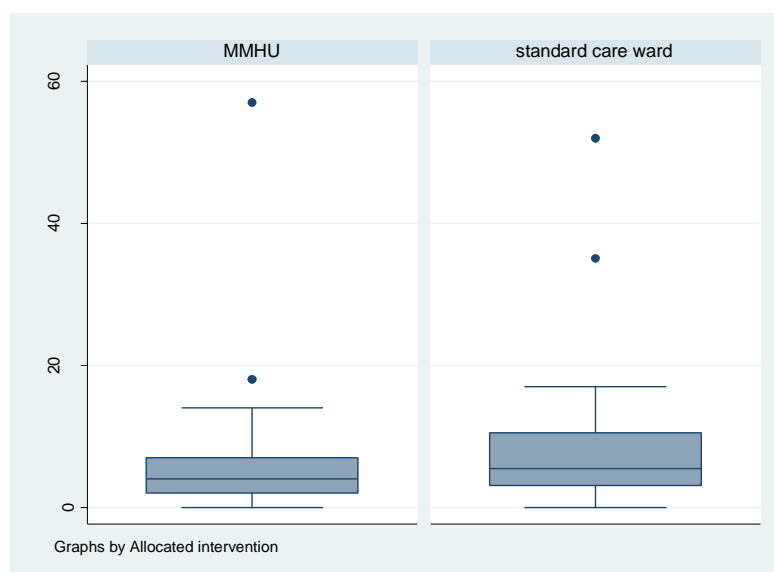**Figure 9: Total Enhancers and Ratio of Patients to Staff and Student**

The median number of detractors per observation was 4 (IQR 2-7) on MMHU and 5.5 (IQR 3-10.5) on standard care wards. The difference between the medians of these results was 1.5 (95%CI -1, 4).The probability that this difference could have occurred by chance was 0.08. The probability that a randomly selected patient from MMHU had a greater number of enhancers than a randomly selected patient from standard care wards was 0.60 (Table 15, Figure 10).

Figure 10: Distribution of Detractors

Graphs by Allocated intervention

Personal detractors were not found to be correlated with the ratio of patients to total nursing staff (healthcare assistants and students) numbers on the day of the observation (r=0.07; p=0.52) (Figure 11).

Figure 11: Total Detractors and Ratio of Patients to Staff and Student
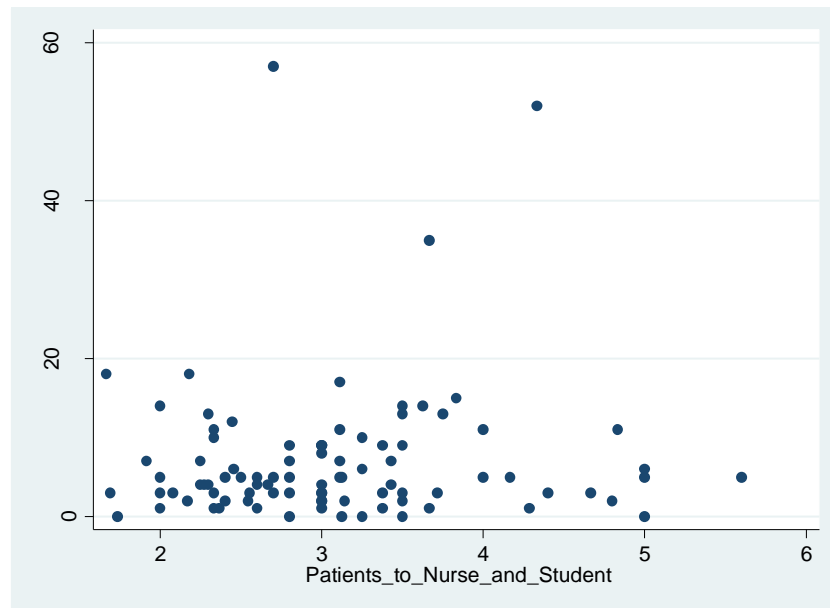
Enhancers

Due to the low number of individual personal enhancers recorded for each
patient, enhancers have been grouped into the categories of comfort
(warmth, holding, relaxed pace), identity (respect, acceptance, celebration),
attachment (acknowledgement, genuineness, validation), occupation
(empowerment, facilitation, enabling, collaboration) and inclusion
(recognition, including, belonging, fun) to allow a statistical comparison (Table
16). Patients on MMHU experienced more enhancers than patients on
standard care wards in the categories of attachment, occupation and
inclusion.

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Table 16: Categories of enhancers

Enhancer	MMHU	Standard Care	P
	Median (IQR; range)	Median (IQR; range)	
Comfort	1 (0-2; 0-10)	0 (0-1; 0-4)	0.06
Identity	0 (0-1; 0-7)	0 (0-0; 0-4)	0.30
Attachment	0.5 (0-1; 0-10)	0 (0-0; 0-4)	0.002
Occupation	0 (0-1; 0-6)	0 (0-0; 0-2)	0.002
Inclusion	1 (0-2; 0-18)	0 (0-0; 0-6)	0.001

The overall breakdown of enhancers by type can be seen in Table 17. This data is clustered, as enhancers experienced by an individual patient are more similar to each other than enhancers experienced by other participants. Standard statistical techniques, which assume independence between observations, are therefore not appropriate and no p-values have been presented. There were more personal enhancers in all categories on MMHU than standard care wards. The dominant categories of enhancers on MMHU compared to standard care wards were: 'including' (44 versus 13), 'warmth' (39 versus 19), 'validation' (33 versus 7), 'relaxed pace' (24 versus 16) and 'fun' (22 versus 3). Examples from the more commonly occurring enhancers are shown below.

Table 17: Details of Enhancers by Ward Type

Enhancer	MMHU	Standard Care	Total
1 Warmth	39 (67%)	19 (33%)	58
2 Holding	9 (100%)	0 (0%)	9
3 Relaxed Pace	24 (60%)	16 (40%)	40
4 Respect	8 (67%)	4 (33%)	12
5 Acceptance	5 (83%)	1 (17%)	6
6 Celebration	14 (67%)	7 (33%)	21
7 Acknowledgement	6 (67%)	3 (33%)	9
8 Genuineness	7 (70%)	3 (30%)	10
9 Validation	33 (82%)	7 (18%)	40
10 Empowerment	1 (100%)	0 (0%)	1
11 Facilitation	28 (80%)	7 (20%)	35
12 Enabling	4 (80%)	1 (20%)	5
13 Collaboration	7 (88%)	1 (12%)	8
14 Recognition	13 (93%)	1 (7%)	14
15 Including	44 (77%)	13 (23%)	57
16 Belonging	4 (57%)	3 (43%)	7
17 Fun	22 (88%)	3 (12%)	25

TOTAL	268 (75%)	89 (25%)	357

Examples of Enhancers from field notes

Warmth

Observation 61 Patient 210 (Iris)

Iris has just returned from a scan. Two senior nurses are with her. One senior nurse says to Iris "hello, are you...." she talks quietly to her "are you frightened". Iris says "I feel sick". The senior nurse says "shall we sit you up a bit Iris?" The two senior nurses sit Iris up. Iris says "oh, oh, oh". The senior nurse says "not too much" "hold my hand Iris, I'll lift the bed up Iris, you're not going anywhere else". The senior nurse adjusts her pillow and holds her hand. She talks quietly to Iris. She gives Iris her buzzer and holds her hand and talks to her quietly.

Respect

Observation 32 Patient 1405 (David)

The occupational therapist was doing a MMSE on David. She had been asking him questions for a few minutes.

She asks 'do you know where you are now?' David replies 'yes, a bit long […]'. The occupational therapist rephrases the question asking, 'where you are now, which building?' David's response is inaudible. David picks up his drug chart. The occupational therapist explains what it is to him and tells him 'you're in the Queen's Medical Centre'.

The occupational therapist continues to talk to David. She says 'can we try something different? Can you take this [a piece of paper] in your left hand, fold it in half and put it on the floor?' David says something inaudible. The occupational therapist reiterates 'take the piece of paper […]'. David does not

complete the task. 'I think we'll give this up' says the occupational therapist 'not coz you can't but when you had your stroke you had problems with your words not your memory; maybe a bit with your memory, but mostly your words'. David responds to this but content inaudible.'

Validation

Observation 86 Patient 1617 (Isaac)

The senior nurse is playing a ball game with Isaac and two other patients on the bay. Isaac is concerned about where his wife is.

'The senior nurse goes back to Isaac and co-patient 1. Isaac talks to her. The senior nurse says "no, she's not here yet". He asks "who's there". The senior nurse says "the only person in the toilet is Bill". She throws the ball to Isaac saying "ready, ready" before she throws.

The senior nurse throws the ball to Isaac again. Isaac laughs. The senior nurse puts co-patient 1's soup down and throws him the ball. Isaac throws the ball to the senior nurse. The senior nurse says "oh you're too quick for me". Co-patient 1 throws a ball at Isaac and the senior nurse says "hey that's better". Isaac talks to the senior nurse. The senior nurse says "she's not in there and she's not been in this morning – she normally comes at......" "do you want me to check? Ok, I'll go and check". The senior nurse goes to the toilet and opens the door and says "no, she's definitely not there Isaac. Do you want any more of your soup?".'

Facilitation

Observation 40 Patient 1443 (Rose)

Rose has been in the activities room for several hours and is now having her dinner there. The activities coordinator has identified that she is struggling with her cutlery.

'The activities coordinator returns [to the activities room] and says to Rose she's going to try something, but it might not work.

The activities coordinator wraps some cling film around the knife. She asks if that helps as she's made it a bit thicker. She gives the knife to Rose. Rose starts to eat with the knife. The activities coordinator says "I meant to cut up". She says she used to have some. [I think she's referring to special cutlery]. Co-patient 1 sings. The activities coordinator asks him who is singing this and is it Al Keele?" She says "it is isn't it?". Co-patient 1 sings again.

Rose eats her dinner. The activities coordinator wraps cling film around the handles of Rose's fork and gives it to her and says "that might make it a bit better". Rose continues to eat just with her knife.'

Including

Observation 15 Patient 1327 (Elsie)

The domestics are cleaning doing a thorough clean of the bay, including all the furniture in the bay. This involves pulling beds out and cleaning all around the bed itself and the floor area underneath it. Two domestics are cleaning Elsie's bed.

'Domestic 1 and Domestic 2 talk as they clean Elsie's bed. Elsie closes her eyes.

Domestic 1 says to Elsie "…. Elsie, Elsie….." "it doesn't take you long, it doesn't take long does it" Domestic1 laughs. Elsie looks around her.

Domestic 1 says to Elsie "it won't take long, it won't be long" She smiles at domestic 1. She says "you're a good man". Domestic 1 says "oh thank you" and laughs. Elsie looks ahead. Domestic 1 continues to chat to Elsie. She smiles at him and talks back to him. Domestic 1 pushes the bed back and says to Elsie "I shan't run you over, your bed's safe with me". Elsie says something. Domestic1 says "oh no, no, I wouldn't do that, I would not do

that at all". "What I'm going to do Elsie, is put this over your legs and cover your legs a bit ok?" Elsie says "yes" and smiles and laughs as Domestic 1 puts the blanket over her legs. Domestic 1 says "that's it, that's it". Elsie looks like she is enjoying the interaction with Domestic 1.'

Fun

Observation 24 Patient 1369 (John).

John is in the activities room.

'The activities co-ordinator looks at the television. A film is on. He rests his arm on John's chair. He says to John "who was that?" John says "Queen Mary". The activities coordinator says "oo, was it?" The film finishes. The activities coordinator says "did you enjoy that". John says "yeah it was good". The song 'There'll be blue birds...' plays on the television. John sings with the activities coordinator.

The activities coordinator turns the film off. A co-patient says "why'd you do that?" The activities coordinator says "coz it's finished, we can listen to the whole song on the radio" The co-patient says "oh, ok". The activities coordinator turns the radio on. It plays the same song.

The activities coordinator squats by John. They sing together.'

Relaxed Pace

Observation 53 Patient 197 (Olga)

'The nurse returns with a jug of water. He pours Olga some water. He moves her table closer and says "now there is...." He puts the tablet in her hand and explains what the tablets are for. He says "put them in your mouth" indicating with his hand what she needs to do. He hands her the glass of water. Olga drinks the water. The nurse stands with her then takes the glass out of her hand and puts the tablet in her hands. Olga is very slow. She touches the tablets. The nurse holds her hand underneath to keep it steady.

He talks to her. Olga takes a tablet. The nurse gives her the glass to have a drink of water. The nurse says "ok…. "and "gone?" "last one, that's the last one". He says "chew it for me". "just chew it for me". Olga takes the tablet. The nurse says "thank you" and leaves the bay. Olga chews the tablet. It takes the nurse 5 minutes to assist Olga in taking her tablets.'

Detractors

Due to the low number of individual personal detractors recorded for each patient, detractors have been grouped into the categories of comfort (intimidation, withholding, outpacing), identity (infantalisation, labelling, disparagement), attachment (accusation, treachery, invalidation), occupation (disempowerment, imposition, disruption, objectification) and inclusion (stigmatisation, ignoring, banishment, mockery) to allow a statistical comparison (Table 18). Patients on MMHU experienced fewer detractors than patients on standard care wards in the categories of attachment and identity.

The overall breakdown of enhancers by type can be seen in Table 19. This data is clustered, as detractors experienced by an individual patient are more similar to each other than detractors experienced by other participants. Standard statistical techniques, which assume independence between observations, are therefore not appropriate and no p-values have been presented. The dominant categories of detractors on MMHU compared to standard care wards were: 'withholding' (119 versus 112), 'ignoring' (72 versus 84) and 'disruption' (31 versus 44). Table 19 gives a breakdown of types of detractors by ward type. Examples from the field notes for these detractors are shown below.

Table 18: Categories of Detractors

Enhancer	MMHU	Standard Care	P
	Median (IQR; range)	Median (IQR; range)	
Comfort	0 (0-3; 0-50)	1 (0-3; 0-36)	0.44
Identity	0 (0-0; 0-4))	0 (0-1; 0-4)	0.04
Attachment	0 (0-0; 0-2)	0 (0-1; 0-5)	0.05
Inclusion	1 (0-1; 0-4)	1 (0-2; 0-6)	0.22
Occupation	1 (0-2; 0-7)	1.5 (1-4; 1-10)	0.19

Table 19: Details of Types of Detractors by Ward Type

Detractors	MMHU	Standard Care	Total
1 Intimidation	1 (100%)	0 (0%)	1
2 Withholding	119 (52%)	112 (48%)	231
3 Outpacing	10 (38%)	16 (62%)	26
4 Infantalisation	9 (31%)	20 (69%)	29
5 Labelling	1 (100%)	0 (0%)	1
6 Disparagement	4 (36%)	7 (64%)	11
7 Accusation	4 (25%)	12 (75%)	16
8 Treachery	0 (0%)	1 (100%)	1
9 Invalidation	11 (34%)	21 (66%)	32
10 Disempowerment	3 (27%)	8 (73%)	11
11 Imposition	3 (30%)	7 (70%)	10
12 Disruption	31 (41%)	44 (59%)	75
13 Objectification	6 (67%)	3 (33%)	9
14 Stigmatisation	1 (100%)	0 (0%)	1
15 Ignoring	72 (46%)	84 (54%)	156
16 Banishment	1 (14%)	6 (86%)	7
17 Mockery	5 (24%)	16 (76%)	21
TOTAL	281 (44%)	357 (56%)	638

Withholding

Observation 1 Patient 100 (Anne)

Anne was opposite a highly distressed patient (co-patient 2) who called out constantly. There are several nurses with co-patient 2.

'Anne says to the nurses "have you finished" the nurses do not respond as their attention is taken up with co-patient 2. Anne says "have you finished; I need to go to the toilet". The nurses do not answer "can I go to the toilet please" The nurses do not respond. Anne gets more insistent "can I go to the toilet please", "can I go to the toilet" "please let me go to the toilet, please". An auxiliary walks by but does not respond. Anne – "please can I go to the toilet" "can I go to the toilet please". No one responds.'

Ignoring

Observation 18 Patient 1339 (Joan)

'Joan is eating her dinner. A pharmacist looks through the charts on Joan's bed. A nurse goes and talks to the pharmacist at the end of the bed. Joan looks at them. Joan is not spoken to by the pharmacist or the nurse.'

Disruption

Observation 11 Patient 118 (Iris)

'The agency nurse is giving personal care to Iris behind a screen. The healthcare assistant looks behind Iris's screen and asks the agency nurse if she can go – 'it's half past'. The agency nurse says "that's a good idea – that's alright".'

Which staff delivered enhancers and detractors?

The mental health trained staff and activities coordinators introduced as part of the intervention were responsible for 44% of the enhancers on MMHU. Activities coordinators were particularly enhancing delivering 35% of all enhancers on MMHU. Student nurses were responsible for 16% of enhancers on MMHU but only 2% of enhancers on standard care wards. The ratio of enhancers to detractors varied between staff groups on MMHU. Staff introduced as part of the intervention had a ratio of 10.6 enhancers to detractors. Existing ward based staff and non-ward based staff had a similar ratio of enhancers to detractors on MMHU and standard care wards and delivered more detractors than enhancers. The student's ratio of enhancers to detractors was higher on MMHU than on standard care wards, which were much more similar to the ward based staff ratio (MMHU student ratio of enhancers to detractors 1.6 versus standard care wards 0.2). Table 20 shows the total number of enhancers and detractors and the ratio of enhancers to detractors for different types of staff observed. Figure 12 and Figure 13 show graphs of this information by staff group.

Figure 12: Bar Chart of Which Staff Groups Delivered Enhancers
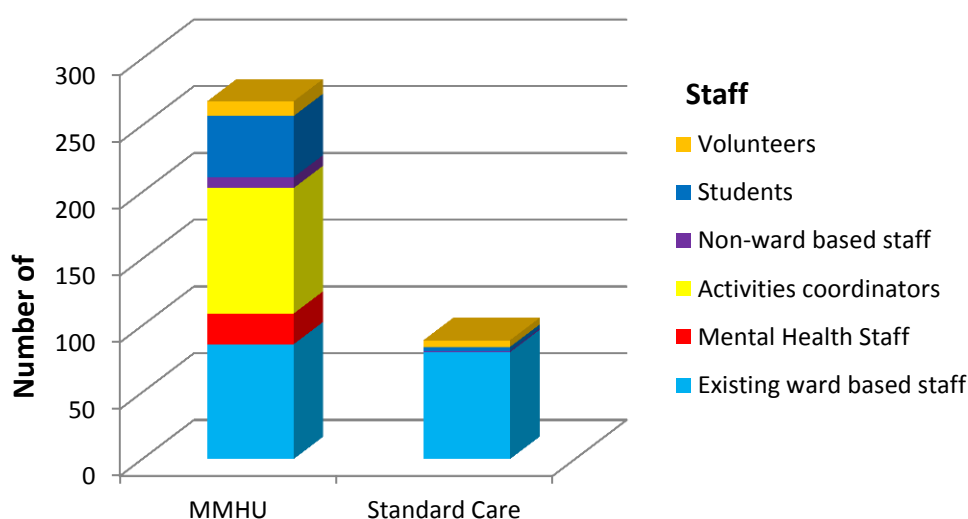
Figure 13: Bar Chart of Which Staff Groups Delivered Detractors
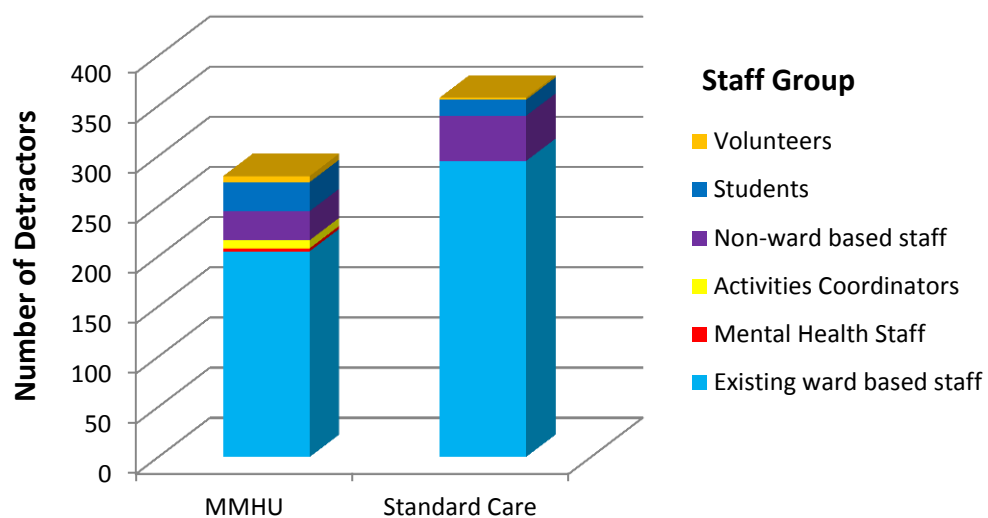
Table 20: Enhancers and Detractors by Staff Type

Type of Staff	MMHU			Standard Care		
	Enhancer 268 (100%)	Detractor 281 (100%)	Ratio	Enhancer 89 (100%)	Detractor 357 (100%)	Ratio
Activities co-ordinators	94 (35%)	8 (3%)	11.8	0 (0%)	0 (0%)	n/a
MHN	13 (5%)	3 (1%)	4.3	0 (0%)	0 (0%)	n/a
AHPs: Physio/OT	10 (4%)	0 (0%)	n/a	2 (2%)	10 (3%)	0.2
Total Additional staff	**117 (44%)**	**11 (4%)**	**10.6**	**2 (2%)**	**10 (3%)**	**0.2**
Doctors	13 (5%)	15 (5%)	0.9	1 (1%)	8 (2%)	0.1
Nurses	51 (19%)	131 (47%)	0.4	55 (62%)	185 (52%)	0.3
HCA	18 (7%)	49 (18%)	0.4	20 (22%)	72 (20%)	0.3
Agency staff	3 (1%)	8 (3%)	0.4	1 (1%)	20 (6%)	0.1
Administrative staff	1 (0%)	2 (1%)	0.5	1 (1%)	0 (0%)	n/a
Ward based staff	**86 (32%)**	**205 (73%)**	**0.4**	**78 (88%)**	**285 (80%)**	**0.3**
Porter/ambulance staff	0 (0%)	0 (0%)	n/a	0 (0%)	2 (1%)	0
Pharmacist/ social worker	4 (1%)	4 (1%)	1	0 (0%)	6 (2%)	0
Domestic	4 (1%)	25 (9%)	0.2	1 (1%)	37 (10%)	0
Non ward staff	**8 (3%)**	**29 (10%)**	**0.3**	**1 (1%)**	**45 (13%)**	**0**
Student doctors	4 (1%)	0 (0%)	n/a	1 (1%)	0 (0%)	n/a
Student nurse	42 (16%)	29 (10%)	1.4	2 (2%)	16 (4%)	0.1
Total Students	**46 (17%)**	**29 (10%)**	**1.6**	**3 (3%)**	**16 (4%)**	**0.2**
	11 (4%)	7 (2%)	1.8	5 (6%)	1 (1%)	n/a
Total Volunteers	**11 (4%)**	**7 (2%)**	**1.8**	**5 (6%)**	**1 (1%)**	**n/a**
TOTAL	**268**	**281**	**1.0**	**89**	**357**	**0.2**

AHP=Allied Health Professional, HCA=Healthcare Assistant, MNH= Mental Health Nurse, OT=Occupational Therapist. Ratio=number of enhancers/number of detractors

5.6.   Conclusion

This chapter has presented the results for the structured, non-participant observational study. Patients on the MMHU spent a higher proportion of their time in positive mood and engagement, experienced more enhancers, less environmental noise, though more noise from other patients calling out repetitively, than those on standard care wards. There was no statistical difference in the total numbers of detractors that patients experienced on MMHU compared to those on standard care wards. However, patients on MMHU did experience fewer detractors in the categories of identity and attachment compared to patients on standard care wards. There was no statistical difference between the two ward types in the proportion of time that patients spent active. Activities coordinators, mental health trained staff and students had the highest ratio of personal enhancers to detractors. The next chapter discusses these results, their validity, how they relate to other literature and implications for practice.

6. Discussion

This chapter discusses the results of the structured, non-participant observation study. It summarises the results of the study, evaluates the study's strengths and weaknesses, and compares the findings to both existing research and literature. The implications of these results and areas for further research are discussed.

6.1. Summary of Results

This study showed that patients on MMHU spent a higher proportion of time in a positive mood and engaged state, and experienced more personal enhancers than patients on standard care wards.   The categories of enhancers which were more often delivered on MMHU compared to standard care wards were attachment, occupation and inclusion. Patients on MMHU experienced less noise overall than those on standard care wards. However, patients on MMHU experienced more noise from patients calling out in distress or repetitively than those on standard care wards. There were more nursing staff and nursing students working the shift being observed on MMHU than standard care wards. This resulted in more staff being present on the bay on MMHU than standard care wards. There was no statistical difference between MMHU and standard care wards for the total number of detractors experienced by patients on MMHU compared to standard care wards; however patients on MMHU did experience fewer detractors, than patients on standard care wards, in the categories of identity and attachment. There was no statistical difference between MMHU and standard care wards in the proportion of time patients spent in an active state, the number of social interactions experienced by the patients or in how often visitors were present on the bay being observed.

Number of enhancers was negatively correlated to the patient to nursing staff (healthcare assistants and student) ratio. There was no correlation between

the number of detractors and the patient to nursing staff ratio (including healthcare assistants and students).

The additional staff brought onto MMHU to perform specific roles were responsible for nearly half (43%) of the enhancers and were the most consistently enhancing in their care with a ratio of 10.6 enhancers to detractors. After this group, students were the next most enhancing group delivering nearly a fifth of enhancers with a ratio of 1.6 enhancers to detractors. On standard care wards the majority of enhancers were from nurses. On both ward types, most detractors were from existing ward based staff (65% MMHU, standard care wards 78%).

6.2.   Strengths and Limitations

The main strength of this study was that it was the first rigorous and systematic evaluation of an intervention to improve cognitively impaired older patients' experiences of general hospital care. Patients were randomised to MMHU or standard care wards, however, recruitment was after randomisation, introducing the risk of volunteer bias [277, 285]. There were no statistical differences between the baseline variables of patients on MMHU compared to standard care wards, but there were some baseline imbalances. Compared to patients cared for on standard care wards, patients cared for on the MMHU had higher levels of behavioural and psychological symptoms (median total NPI score 28 versus 19, for the 65 patients where an NPI score was recorded), were more likely to have come from a care home (24% versus 11%) and were less functionally dependent (Barthel Index $\leq$5 26% versus 39%). Patients sub-sampled for observation on standard care wards were more likely to be cared for in a side room than those on MMHU thus preventing observation (3% versus 9%). When randomising patients, baseline imbalances are often seen when there are multiple baseline variables. It is likely that the effect of these baseline differences would have been in different directions. Patients with higher behavioural and psychological symptoms might have had a worse experience, but those

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patients less disabled may have had a better experience. Patients admitted from a care home are likely to have more disability or more behavioural and psychological symptoms. The most common reasons for caring for patients in a side room are: infection control (MRSA or clostridium difficile), palliative care or to segregate a patient calling out disruptively from other patients. It is likely that these patients would have had a worse experience of care.

The study was large scale and involved 540 hours of observation over a 10 month period. No other studies of older people with cognitive impairment have undertaken so many hours of observations in the general hospital. The real time direct observations allowed an assessment of real life routine care as well as 'highlights' such as therapy and activity sessions. A single patient was observed at a time, reducing distractions arising from observing groups of patients, when attention would be drawn to action, rather than inaction. However, as it was not possible for the researchers to be blinded to the ward type, there was the opportunity for bias. Extensive measures were taken to minimise the risk of bias. The Dementia Care Mapping tool was applied rigidly, allowing dispassionate reporting and always from the point of view of the person being observed. As a consequence, care was recorded as being withheld even if the member of staff was dealing with the greater needs of another patient. The rigid applying of rules also understated the extent of the difference between the two ward types. Two researchers made the observations which allowed some assurance of reliability and objectivity. Consistency was developed by thorough training, and inter-rater reliability was measured directly. Neither of the researchers had any involvement with the development of the MMHU or the clinical care of the patients.

There could have been a Hawthorne effect [157]. Staff may have known that they were being observed and improved or modified their behaviour in response. All MMHU ward staff received generic person-centred care training. Two members of staff (the ward manager and a deputy ward manager) had received Dementia Care Mapping training during the development of the intervention (but never used it in practice). Three others

(one staff nurse and two mental health nurses) had received Dementia Care Mapping training many years ago. It is not known whether any standard care ward staff had received Dementia Care Mapping training. This could have given the MMHU staff an advantage over standard care wards. However, the seniority of the staff receiving recent Dementia Care Mapping training meant they had less direct patient contact than the staff nurses who received the generic person-centred care training and would have had little impact on the results. The patients' experiences of care were also likely to be affected by many other aspects of the intervention such as the provision of organised activity, the change in skill mix, the enhanced environment and the proactive and inclusive approach to family carers.

There were some specific limitations of the study design. Observations were not made overnight, the researchers only had limited knowledge of patients observed and initially had limited experience in using the Dementia Care Mapping tool. Dementia Care Mapping was not developed for patients with delirium or for the general hospital setting. All these limitations applied equally to both ward types.

This research was conducted in a single NHS hospital trust which limits the generalisability of the findings. However the hospital provided the sole emergency medical service for its local population and was likely to be representative.   The MMHU was a single ward and it may have worked differently with a different group of ward staff. The findings of this study suggest that patient experience of care can be improved by specialist units, but these findings require replication.

6.3.   Context and Comparison to Other Literature

There were no previous studies (and no studies could be identified that were in progress) that compared the cognitively impaired older patients' experiences of care on a specialist ward to other wards.   Extensive efforts were made to verify this statement. Experts in the field were contacted (Dr Claire Surr, lecturer in dementia studies, Bradford Dementia Group; Paul

Edwards, Head of Training and Practice Development, Bradford Dementia Group; Dr Rosie Woolley, National Audit of Dementia project manager (observational audit) and Research Fellow in the Academic Unit of Elderly Care; Prof Dawn Brooker, Director of the University of Worcester Association for Dementia Studies and Prof Rowan Harwood, Professor of Geriatric Medicine Nottingham University Hospital). The substantial amount of literature reviewed for this thesis did not identify any similar published studies. Sheehan also concluded that little was known about how people with dementia experienced hospital care [286]. The literature on person-centred care for people with severe dementia comprised a large number of articles that were based on clinical experiences, personal opinions and anecdotal evidence [53]. The NHS Confederation's report on improving the hospital care for people with dementia included no research-based interventions for improving the quality of care that the patient would have directly experienced [287].

Other hospitals have been developing 'dementia friendly' wards. These included projects at Taunton and Somerset NHS Foundation Trust and the Royal Wolverhampton Hospitals NHS Trust (New Cross Hospital) [288]. These projects are not being evaluated by controlled clinical trial. The quality of care offered by New Cross Hospital is being evaluated by family and staff interviews and surveys, complaints and compliments and using data from the National Audit of Dementia.

Compared to patients on standard care wards, patients on MMHU spent more time in positive mood and engagement. The median difference in the proportion of time patients spent in positive mood and engagement, between the two ward types, represented an additional 40 minutes out of the six hour observation period. The most significant area of improvement was that patients on MMHU spent 30 minutes less time in a mildly negative mood or disengaged state compared to patients on standard care wards (median difference 9%, p=0.05). Patients on MMHU also experienced more enhancing behaviours than those on standard care wards. Enhancers were found to be

negatively correlated to the patient to staff (and student) ratio. These findings could have related to the enhanced staffing and skill mix on MMHU compared to standard care wards and their corresponding greater presence on the bays.

There have been concerns raised about nurse staffing levels on healthcare of the older people wards. Tadd [60] discussed untenable staffing levels on wards for older people which resulted in care which failed to protect and promote an individual patient's dignity. The Royal College of Nursing survey of staffing levels found for staff working in Healthcare of the Older Person a ratio of 48%/52% registered to unregistered nurses and an average of 5.2 patients per staff member [289]. The Royal College of Nursing advised that to provide good quality care on Healthcare of the Older Person wards there should be a ratio of registered to unregistered nurses of 65%/35% and a ratio of patients to staff of between 3.3 and 3.8. They considered that the same ratio of patients to staff but a ratio of 50%/50% registered to unregistered nurses would be sufficient to provide just basic safe care. A survey of carers of people with dementia (n=1478) and people with dementia (n=6) reported that 96% of respondents considered low staffing levels to be a barrier to delivering good quality care [290]. A survey of healthcare professionals found that 75% considered staffing levels to be a barrier to delivering good quality care [291]. There are no guidelines on the advised level of mental health trained staff on a Healthcare of the Older Person ward.

The patient to staff ratio for MMHU showed that according to Royal College of Nursing guidelines there were sufficient staff to deliver high quality care. However, the Royal College of Nursing's figures were based on Healthcare of the Older Person wards. Research has shown that cognitively impaired older patients are more functionally dependent and have more neuropsychiatric problems than older patients with depression [17]. A specialist medical and mental health unit where all patients were cognitively impaired would have required a higher ratio than a standard Healthcare of the Older Person ward to deliver high quality care. Despite the improvements shown in patients'

mood and engagement and numbers of enhancers on MMHU compared to standard care wards, at least a quarter of patients on MMHU experienced 21% of their time in negative mood or disengaged and a quarter of patients experienced no more than one enhancer during the six hour observation. Nottingham University Hospital used the Association of UK University Hospitals (AUKUH) tool [292] to model necessary ward staffing levels. This tool showed that staffing for the MMHU was underprovided by 6 whole time equivalent nursing (registered and unregistered) staff for the level of dependency of the patients [293]. Clinical managers were investigating these figures, but the improved staffing levels on MMHU may still have been insufficient to consistently deliver high quality care. At least half of patients cared for on standard care wards spent 20% of their time in negative mood or disengaged and at least half experienced no more than one enhancer during the observation. This result may have been due to standard care wards having at times insufficient staff to deliver basic safe care. The Royal College of Nursing reported the current ratio of staff to patients as 1:4.6 [294]. This ratio was worse than those usually observed during this study.

There were more enhancers delivered on MMHU than standard care wards in the categories of attachment, occupation and inclusion. Most patients only experienced enhancers in the category of comfort on standard care wards. The additional enhancers on MMHU compared to standard care wards were mostly from the staff brought in as part of the intervention (specifically the activities coordinators) and the student nurses. It was the activities coordinator's function to provide enhancing care. These results provided evidence that they did their job well. Davies's [295] focus groups on factors older people considered important for a good experience of care included the importance of being able to build relationships with genuinely interested staff. The activities room and the work of the activities coordinators gave a space where this could happen, away from the busy environment of the ward.

Student nurses accounted for 42 enhancers on MMHU compared to 2 on standard care wards, a striking difference which was not accounted for by the more frequent presence of students on MMHU than standard care wards. Allocation of student nurses was essentially random and there was no reason to believe there was any difference in the calibre of student nurses allocated to MMHU. Concerns have been raised that nurses are being recruited with insufficient compassion to care for older people [22]. This finding provides evidence that the right people are entering nursing and that lack of compassion relates more to the environment, culture, expectations, welfare, leadership and organisational factors than attributes of the individual. It also suggested the environment and ward based staff facilitated or validated the students behaving in an enhancing way.

There was no difference between the two ward types in number of enhancers delivered by the nursing staff. Overall, there was no difference in numbers of detractors that patients experienced on MMHU compared to standard care wards. This has implications for the use of person-centred care training to improve quality of care in the general hospital. Hennelly [296] had called for staff of all levels working with dementia patients in the general hospital to be educated, trained and supported in the management of these patients in a challenging environment. However, Hennelly cited no research evidence in a general hospital evaluating the effect of introducing such training.

The predominant detractors, and the categories to which they belonged, were withholding (comfort), ignoring (inclusion) and disruption (occupation). At least half of patients on MMHU experienced no detractors related to comfort, but the range of values suggests a small number of patients on both ward types experienced a very high number of detractors in this category. (25% of patients on MMHU experienced between 3 and 50 detractors related to comfort; 25% of patients on standard care wards experienced between 3 and 36 detractors related to comfort) These detractors are likely to relate to patients whose needs are so high (such as those who repetitively call out) that ward staff find it difficult to meet them irrespective of the amount and quality

of person-centred care training given. The higher number of detractors on MMHU in this category may also relate to the imbalance in behavioural and psychological symptoms (neuropsychiatric inventory scores) of patients on MMHU compared to standard care wards.   There was no difference between the two ward types in detractors in the categories of inclusion and occupation. Staff working in the presence of patients as if they are not there (ignoring) or intruding in or interfering with something a patient is doing (disruption) are both areas that person-centred care training should have improved. There is a need for training, but also for senior management to ensure that such training is implemented.   However, the person-centred care training and introduction of the personal profile ('About Me') document did appear to have had an effect on detractors related to identity and attachment, which were seen less often on MMHU than on standard care wards.

Woolley's [232] study to provide evidence of the feasibility of Dementia Care Mapping on a hospital ward found much higher levels of enhancers and lower levels of detractors. However, the patients in this study were less cognitively impaired, with half able to give informed consent, which may explain some of the difference. Two of the five wards observed were in a community hospital and the patients would have been less ill. In addition, as noted earlier, there were no data on inter-rater reliability of identifying enhancers and detractors, so it was not possible to be sure that enhancers and detractors were coded in the same way.

The high number of detractors that patients experienced on both ward types provided evidence that sometimes patient experience of care was not good. NICE has produced a booklet informing people who used the NHS services about the experience of NHS care they should expect. The booklet informs users of the NHS that they should expect to be treated as an individual: with respect, kindness, dignity, compassion, understanding, courtesy and honesty. Patient's confidentiality should be respected and they should never be talked about in their presence without being included in the conversation. Patients

should get help with basic needs [297]. Many of the detractors demonstrated that at times, on both ward types, the patients in this study did not experience the good NHS care they should have expected.

There was no statistically significant difference in the proportion of time patients spent active on MMHU compared to standard care wards. However, as discussed above, there was a difference in the number of enhancers related to occupation delivered on MMHU compared to standard care wards. The extent of boredom and inactivity on a hospital ward and the importance of such activity to support rehabilitation and recuperation had been commented on by The Older People's Commissioner for Wales. They found the absence of social activity and meaningful engagement was one of the most powerful impressions following a hospital visit [23]. The Alzheimer's Society have called for the provision of more occupation for patients with dementia when in hospital [20]. The Royal College of Nursing has made a commitment to the care of people with dementia in the general hospital which includes the provision of appropriate activity to encourage social engagement, maintenance of function and recovery and adequate space and resources to support activity [298].

Dementia Care Mapping is known to overstate activity [238]. An inactive patient who briefly scratched his head would be scored as in an active behaviour category code for the five minute period. This effect may have overstated activity on standard care wards where patients were observed to spend a lot of time in an inactive state. The power calculation for this study was only for the primary outcome measure of proportion of time in positive mood and engagement. The study was under powered to detect a clinically significant difference of around 30 minutes extra time in an active state. In addition, quantity of activity may not be related to quality of care and could be an insensitive measure [193]. Patients' experiences of care are likely to be related more to the quality of activity than quantity.

Noise in the environment is likely to impact on patient experience. Noise from electronic alarms and equipment was less on MMHU compared with standard care wards. However, noise levels were still high with an alarm, background noise or another patient calling out being heard for the majority of the day. The noise of hospitals has been found to adversely affect patient experience [36, 44, 103]. The evidence on the effect of noise levels on patients is largely based on expert opinion. Noise is considered a primary cause of sleep deprivation and disturbance among patients [299]. It increases patient anxiety and decreases their confidence in the clinical competence of the staff. It contributes to patient falls, causes confusion and results in increased medication and restraint use (though physical restraint is almost never employed in the UK) [300]. People with dementia exposed to periods of continuous noise can experience greater impairment in memory and other cognitive functions, increased agitation, less tolerance for pain and feelings of isolation [301]. This then affects the person's ability to understand and cope with aspects of care and treatment. Ultimately, it can lead to the person seeming to resist or decline care. Constant telephones and call bells (buzzers) can be overwhelming for patients [302]. A calm, safe and welcoming environment is necessary to promote person-centred care [53]. An environment full of noise or where patients call out repetitively 'help me, help me' feels neither calm, safe nor welcoming.

There was more noise from patients who called out or repetitively vocalised on the MMHU than standard care wards. Maslow discussed the basic human need of a person to feel safe [303]. It was possible that some patients did not feel safe on MMHU due to other patients continuously calling out in distress. When there was a patient on the bay being observed to be repetitively calling, the environment of MMHU was probably unpleasant to the patient being observed.

6.4. Dementia Care Mapping in the General Hospital

Woolley concluded that it was feasible to perform Dementia Care Mapping on a general hospital ward [232]. This study supported that conclusion, but found that the Dementia Care Mapping tool needed to be adapted to be useable in the general hospital. At the time of this study, there was no published research using Dementia Care Mapping to evaluate an intervention in an acute hospital. As a structured, non-participant observational tool, Dementia Care Mapping worked reasonably well. The behaviour category codes were tightly defined and included examples of hospital care. The mood and engagement scores were sufficiently well defined to allow good inter-rater reliability. However, the Dementia Care Mapping manual gave insufficient details about enhancers and detractors. Considerable effort was needed during the pilot period to ensure both researchers were coding consistently for enhancers and detractors. The examples of enhancers and detractors given in the manual were more applicable to a care home environment than an acute hospital. In addition, when no staff were on the bay, no detractors could be recorded, even when an evident need of the patient was not being met. This made it more likely for MMHU staff to be recorded as 'withholding' as they were more frequently present on the bay than staff on standard care wards.

The additional rules developed for this study to code detractors were based on discussions with academics and clinicians who worked with people with cognitive impairment and the researchers' observations of care on the wards during the pilot period. The hospital environment was not one which promoted privacy. The coding decision not to score detractors if screens were used but conversation with clinicians could still be heard made allowances for these limitations. Not to do this would have resulted in many more detractors being scored on both ward types for situations outside the control of the ward based staff. The coding decisions also allowed enhancers to be scored when staff made a particular effort to protect privacy through the use of hearing devices or visual aids not normally seen on a hospital ward.

The literature on privacy is based on interviews with cognitively intact older people. Older people prefer the camaraderie of being on a hospital bay rather than the isolation of a single room. When interviewed in hospital, they expressed relatively little concern over the loss of privacy being on a hospital bay [23]. Observations of patients in hospital noted that patients don't always like the screens being closed [304]. However, older people did appreciate staff's attempts to ensure privacy by using the screens and lowering their voices when speaking even when care was not particularly intimate [295]. Similarly the coding decision not to score detractors if staff used colloquial endearments (provided they used the patient's name to begin with) may have been contentious. Older people like to be referred to by their preferred name [60, 295]. However, to assign a detractor every time a colloquial endearment was used would have resulted in some very high quality interactions being coded as detracting. Use of these terms could also be interpreted as warmth.

Dementia Care Mapping did not fully capture small actions which individually were not coded as an enhancer, but, when the ward based staff collectively and regularly did them, may have had a significant effect on the health or well-being of the patient. For example, saying "good morning" to a patient was not recorded as an enhancer. However, when a patient walks down the walkway and every member of staff greats them with "good morning", it creates a very warm welcoming atmosphere (Tadd commented that older people consider being acknowledged by staff walking past as particularly important [60]). Similarly, giving a patient a brief prompt to drink "drink your tea Jack before it gets cold" was not scored as an enhancer. However, when all staff gave frequent prompts to patients to eat and drink, this technique appeared very effective at getting patients to eat and drink more.

Dementia Care Mapping was designed for use in the community. The primary objective of the general hospital was to get the patient well, or with their condition managed, and discharged back to the community. It was also important that during this time the patient did not suffer unnecessary deterioration in their cognitive or functional state. Therefore the most

important activities of the staff were those aimed at achieving these objectives. Dementia Care Mapping did not differentiate between care which met these objectives and emotional and psychological care. The codes were also more focused on leisure activities than personal care, with 5 different codes for leisure (singing and music, reminiscence, sport or exercise, leisure, engagement of the senses), but only one code for a range of personal care activities (being washed and dressed, pushed in a wheelchair, given medication, physiotherapy, physical examinations). A tool needs to be developed which meets all the objectives of general hospital care.

6.5. Interpretation and Implications

The conclusion from this research was that the patients' experiences of care on the Medical and Mental Health Unit was better than the patients' experiences of care on standard care wards. This improvement was achieved on a ward where all the patients were cognitively impaired, compared to approximately 61% being cognitively impaired on a Healthcare of the Older Person ward [17]. Some feel that the burden on staff to care for patients on a ward where all patients are cognitively impaired would put significant strain on staff [85]. This study has demonstrated that staff could provide, and sustain, better care for patients on a ward where all patients were cognitively impaired. The results were also obtained despite using the relatively insensitive tool Dementia Care Mapping.

The following sections discuss the implications of this research for patients, their carers, practitioners, hospital management and healthcare commissioners and future research needed.

6.5.1. Implications for the Patients, Carers, Practitioners and Hospital Management

Patients with cognitive impairment and their carers will be pleased to know that hospitals can improve the quality of their experience by caring for them in specialist units which incorporate best practice dementia care. For practitioners this study shows the effect of their actions and inactions and

that practice can be improved. Practitioners should also be interested in the potential for student nurses to improve patient experience and the need to encourage and support them to be person-centred in their practice. Hospital management should be interested in the finding that person-centred care training alone may not always improve patient experience. Consideration needs to be given to the staff skill mix and quality assurance systems need to be in place to ensure training changes practice on the wards. Dementia Care Mapping could be valuable for quality assurance and development in services, although it remains expensive and labour intensive to use. Person-centred care training alone is an insufficient intervention to meet the needs of some patients, particularly those who repetitively call out. Practitioners and hospital management need to identify and support innovative interventions to improve the hospital care of patients with very high psychological needs. Both practitioners and hospital management should be interested in the high noise levels in the patients' environment and take measures to reduce electronic noise in the ward. For patients, their carers, practitioners and hospital management, the evidence from this study empowers the argument that cognitively impaired patients' experiences of care in the general hospital can be improved.

6.5.2. Implications for Healthcare Commissioners and Funders

This research provides evidence that the intervention of the MMHU did improve patient experience of care which was one of the five domains set out in the NHS Outcomes framework 2012/13 [30]. As such it should be of interest to healthcare commissioners. This research gave evidence on the process of care and which parts of the intervention were most successful. It also demonstrated that the intervention (MMHU) was different to the control (standard care wards). A measure of process and fidelity of complex interventions was recommended by the Medical Research Council [305].

This research should be seen in the context of other outcome measures from the randomised controlled trial of the MMHU compared to standard care, the

health economic evaluation and patient, carer and staff interviews, which are yet to be finalised and published. An original intention of the MMHU development was to have an intervention sufficiently different from standard care to have a reasonable chance of demonstrating health status outcomes in a trial [97]. This non-participant observation study showed that, in some respects at least, this had been met.

At a National level, in the UK, decisions on commissioning are made by the National Institute for Health and Clinical Excellence (NICE). The quality adjusted life year (QALY) is used as the metric on which to base prioritisation decisions [306]. The quality adjusted life year is a calculation of the extra years of life an intervention resulted in adjusted for the quality of life the patient had following the intervention [307]. The Euroqol EQ5D instrument [308] is the usual measure of quality of life. An additional dementia specific quality of life measure used in the NIHR TEAM trial is DEMQOL [189]. Vergel and Sculpher[306] raised some concerns with the use of quality adjusted life years which are relevant to the patients in this study. Firstly, patient characteristics such as starting health or age are not taken into account by the QALY. The EQ5D is a crude measure, with only three points per dimension and clinically important improvements in the patient's ability to self-care or walk may not be measurable on the EQ5D. Such improvements may also not be what were most valued by the person [306]. In addition, the 90 day mortality rate in the NIHR TEAM trial was 24% [unpublished data] and in a related cohort study 180 day mortality was 31% [309]. Many patients are reaching the end of their natural life and improvements to the healthcare they received may have made no difference to this outcome, whilst patient experience becomes paramount.   The use of quality adjusted life years in economic evaluations means that potentially important health consequences are excluded. Such decision making does not necessarily reflect what the public want from healthcare [310]. It is an anomaly that whilst patient experience of care is one of the domains of care for the NHS Outcomes Framework, used to commission services, it is not included by NICE evaluations of services. Coast

argued that a better approach was considered cost-consequence comparison [310]. Such an approach tabulates all the relevant costs and consequences of healthcare options. It includes both quantitative and qualitative information.

This research adds important information on both the patients' experiences of care and the process of care for patients on the MMHU compared to standard care wards in the hospital. It would be important for use by healthcare commissioners as part of the cost-consequence evaluation of the MMHU.

6.6.   Future Research

This study identified further areas for research.

1.   Qualitative analysis of field notes

A qualitative analysis of the detailed field notes could illuminate or advance the understanding of how MMHU differed to standard care wards and what factors affect the enhancing or detracting behaviours.

2.   Patients calling out ('persistent vocalisation')

There is an urgent need for innovation and research on interventions to improve the care of older people who called out repetitively.   Possible interventions included a well-staffed challenging behaviour unit. Such a unit would optimise the environment by providing a low stimulus, calming environment for patients who called out repetitively. Staff caring for them would need to be skilled at communication and interventions to reduce distress. In addition, or alternatively, a care planning tool to act as a decision aid could be developed. Such a tool could adapt Barton's (2005) nine steps to care for patients with disruptive vocalisation [311] and a systematic review of more recent literature on interventions to reduce disruptive vocalisation in the general hospital environment. It would take the nurse through decisions on communication, pain, eating and drinking, toileting, company, sedation and the use of side rooms. Content validity would be gained by a Delphi exercise of expert opinion on what items should be included in the tool. A

before and after study design would be used to establish how effective the tool was in practice. It would be aimed at ensuring where possible, all the patient's needs were met, but where there were no identifiable ways of meeting all the patient's psychological needs, then the tool would support staff care planning to meet the patient's basics needs for food, drink, the toilet, pain control and rest in a systematic, respectful and dignified way.

3. Organised activity

Organised activity was very successful at improving patients' mood and engagement and at providing enhanced care which gave the patient occupation, a sense of identity and included them socially. However there were times on the ward that organised activity was not available to patients. Volunteers were noted, in general, to be enhancing in their behaviour towards the patients, and where they were detracting, it tended to relate to the use of colloquial endearments such as "sweetheart" and "love". Education could easily prevent this. However, volunteers were rarely seen on any wards. The importance of volunteers had been recognised and there had been calls for hospitals to increase the number of volunteers [312]. Volunteers give their time for free and were often keen to help. An ethnographic research study on the volunteer service to understand the organisational and other barriers to volunteering on Healthcare of the Older Person wards is needed.

4. Noise

Further research is needed into non-auditory methods of alerting staff to patients' requests for assistance. Alarms introduced to improve safety had resulted in high levels of irritating noise, which prevent rest and recuperation and may have distressed and agitated patients. Patients spent a significant amount of their day with no staff on the bay, and thus buzzers and equipment alarms were the only way to attract a member of staff's attention (though not all patients were able to use a buzzer to gain attention). When using auditory alarms, there would never be a quiet environment on a hospital ward as the

alarm must sound for action to be taken. Research is needed into the effectiveness of visual alerts for the patients to call for attention or the effectiveness of very regular visits 'rounding' (up to every 30 minutes) from staff to identify patient needs.

6.7. Conclusion

The aim of this thesis was to contribute to the evidence base on the improvement in the quality of experience of cognitively impaired older patients in hospital. This aim was achieved. A review of published evidence concluded that the best way to measure patient experience was by structured, non-participant observation. A systematic review of non-participant observational tools identified the most suitable tool – Dementia Care Mapping. A research design was developed to allow a study which compared the experience of care of patients on different ward types, using patients who had been randomly allocated to their admission ward, within the constraints of a NHS hospital. The findings from this research contributed to the knowledge base on cognitively impaired patients' experiences of care in the following ways:

1. Patient experience of care could be improved by Medical and Mental Health Units.

2. The Medical and Mental Health Unit was distinctly different from standard care wards in terms of how staff behaved towards patients, noise levels and staffing levels.

3. Patients on MMHU experienced less overall noise, but more noise from patients calling out than patients on standard care wards.

4. Dementia Care Mapping has been successfully adapted to be used in the acute hospital to evaluate an intervention.

In summary, a medical and mental health unit with enhanced staffing numbers and skill mix, that adopted a patient-centred approach to care, adapted the environment to be more appropriate, stimulating and welcoming to older people with cognitive impairment, provided a

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programme of high quality organised and therapeutic activity and adopted an inclusive and proactive approach to carers was a model of care which improved patient experience.

This thesis forms an original piece of work in that:

1. It was the first randomised study of the cognitively impaired older patients' experiences of care on a medical and mental health unit.

2. It was the first time Dementia Care Mapping had been used, in the general hospital, to evaluate an intervention.

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Appendix 1: Training Courses Attended

Course	Organiser	Date	Duration
The Nottingham Systematic review Course	The University of Nottingham	June 2012	4 day course
Nvivo9 basic and advanced	QSR	March 2012	2 day course
Advanced User Dementia Care Mapping	Bradford Dementia Group	Nov 2010	4 day course
Basic User Dementia Care Mapping	Bradford Dementia Group	Nov 2009	3 day course
Advanced Statistics	University of Nottingham	May 2010	13 week post graduate level module in Public Health
Research Methods in Epidemiology with Basic Statistics	University of Nottingham	Jan 2010	13 week post graduate level module in Public Health
Referencing and citing using Endnote	University of Nottingham	2009	1/2 day course
Presentation skills for researchers	University of Nottingham	March 2010	1 day course
Observational and ethnographic research in Social Science	University of Nottingham	2009	1/2 day course
Critical analysis of scientific literature	University of Nottingham	Jan 2010	1/2 day course
Good Clinical Practice	Ashford and St. Peter's Hospital	June 2010	On line course

Appendix 2: Table of Tools to Measure Patient Experience

Author, year, country	Name of instrument	Behaviour measured	Recording	Training	Observation and Setting	Reliability	Validity
Bowie and Mountain [186], (1993), UK	Patient behaviour observational instrument (PBOI)	Types of behaviour: self-care, external engagement, reception of care, motor activity, anti-social, inappropriate and neutral.	Hand held device (Psion organiser)	Trial related training	13 x 5 minute observations every hour over 1 day. Long stay hospital wards for the confused elderly.	Kappa 0.85	Content validity – behaviours derived from video-taping of residents followed by the arrangement of all behaviours into an exhaustive and mutually exclusive category system. Construct validity – the PBOI differentiated between wards rated on environmental quality.
Smallwood, (2001) [188], UK Macdonald [313], (1985), UK	Short Observational Tool.	Type of Behaviour: neutral, motor, self-care, receiving care, external behaviour and inappropriate behaviour.	Video recorded	Not stated	2 x 15 minute observations over 2 days between 10am and 4pm. Dementia wards.	IRR 87%	Divergent/convergent validity shown by the correlation of each behaviour with the total of every other category. The only two behaviours which were positively correlation were motor behaviour and inappropriate behaviour indicating that these may be measuring the same phenomenon. Test-retest reliability All dimensions except external behaviour showed reliability over time.

Author, year, country	Name of instrument	Behaviour measured	Recording	Training	Observation and Setting	Reliability	Validity
Van Haitsma [204], (1997), US	Observer-Behaviour Streams	Behaviour: pathological verbal, sleeping, null, socialising, radio/TV, group activity, religious activity, walking, gazes with interest, handles objects.	Hand held computer (Psion organiser)	Trial related training.	16 x 10 minute intervals over 3 weeks. Special care unit nursing home.	IRR 85.5% behaviours. 97.8% location 96.2% position	Convergent validity calculated against informant scales. A priori predictions made of expected results, however, no prediction made of acceptable correlations. Correlations low.
Lawton [222] (1996), US	Apparant Affect Rating Scale	Emotions: pleasure, anger, anxiety/fear, sadness, interest.	Hand held event recorder	One month, discussions, video coding, observations.	16 x 10 minute streams over a four week period for each resident time sampled throughout the day. Special care unit nursing home.	Kappa 0.76-0.89	A priori assumptions made to correlations but not strength of associations. Convergent and divergent validity tested.
Ward [224] (1992), UK	Observational scale (no specific name)	Problem and positive behaviours; presence of personal care, eating and mobility. Focus on negative behaviours such as aggression, extreme moods, repetitive activity.	Hand recorded	Training not stated	Observation over 10 seconds. Behaviour occurring during final second noted during the next 10 seconds. 10 x 14 minute periods over one week. Psychiatric wards.	Percentage agreement for occurrence and non-occurance . Overall agreement 95%; range 25-97%	Content validity from transcripts of observations of patient on the ward.

Author, year, country	Name of instrument	Behaviour measured	Recording	Training	Observation and Setting	Reliability	Validity
Wood[226], 2005, Australia	Activity in context and time (ACT)	Records environmental domains (activity situations, how the environment enables social and physical interaction); Time-use domains (gaze, position and movements, conversational exchanges, participation in tasks and activities or problematic behaviours) and apparent affect (interest, no affective expression, anger, sadness or depression, anxiety or fear, pleasure).	Hand held computer	Training not stated.	Data collected on each participant every 10 minutes from 8:00am to 8:00pm across four non-consecutive days. Alzheimer's disease special care unit.	Weighted kappa 0.65-0.99 across all domains.	Content validity based on extensive preliminary observation at the study site to develop six mutually exclusive and exhaustive activity situations. Apparent affect uses Lawton's apparent affect rating scale (see above).
Stewart[227](1999), Canada Morgan and Stewart[314] (1998)	Environment-behaviour interaction code (EBIC)	Behaviour of subject and others involved in social interactions. Categories include physical social, physical asocial/non-social, verbal, vocal, non-verbal. And environmental impact (positive, neutral, negative).	Hand held computer	12 hours training including lectures and practice observations on video segments of interactions illustrating behaviours	4 x 30 minute observations. Long term facility dementia care unit.	Kappa 0.65, IRR 78%.	Test-retest pearson produce-moment correlation r=0.5-0.93 Construct validity from known groups method; content validity through nonparticipant observation and manual recording by two observers, analysis of existing instruments, and review of behavioural categories by two clinical nurse specialists with expertise in dementia care.

Author, year, country	Name of instrument	Behaviour measured	Recording	Training	Observation and Setting	Reliability	Validity
Sloane[118] (2007), UK	Dementia Care Mapping	Mood or engagement, activity and quality of staff interactions	Hand recorded	Accredited training from the University of Bradford.	Observations coded every five minutes for 6 hours. Residential and nursing homes, assisted living facilities and day centres.	IRR of 80%.	SEE SECTION 3.6.2
McCann[203] (1997), US	No Name – time sampling technique	Resident behaviours: location, directed activity, alertness, facial affect expression, behavioural ratings	Hand Recorded	One month of training including discussion of codes and then practice observations with project director	60 five minute observations done five times per day over 12 consecutive days. Nursing Homes.	IRR 90% during training period.	Content – codes derived from clinical and empirical data and tested in the field.

Author, year, country	Name of instrument	Behaviour measured	Recording	Training	Observation and Setting	Reliability	Validity
McFaydn[228] (1983) UK	Measurement of Engagement in the Institutionalised Elderly.	Independent self-care, leisure, walking, other non-deviant behaviours, dependent self-care, watching, deviant behaviour, doing nothing, sleeping.	Hand recorded	Trainer outlines categories, simultaneous observations with trainer and trainee, - comparisons made and discussed, Simultaneous observations without discussion IRR calculated, Coding of each other's observations and calculation of IRR	Various dependent on study. Older persons care homes, psychiatric wards, geriatric wards, general hospital wards, geriatric psychiatric wards.	IRR>90%	Divergent validity – engagement is not correlated with measures of cognitive impairment.
Felce[182] (1980) UK	Measure of Engagement in Activity	Engagement: interacting with another person, using recreational materials or material connected with daily living activities or mobility.	Hand Recorded	The paper states that a handbook was written to instruct researchers in the measure of engagement in activity.	Insufficient detail given in the paper. Homes for the elderly and geriatric hospital.	IRR 43%-100% kappa 0.83-0.94	Face validity by showing the graphs of engagement to the Sisters of the two hospital wards and the superintendent physiotherapist who ran the central lounge. They agreed that the graphs gave a realistic representation of levels of activity in different areas during the day.

Author, year, country	Name of instrument	Behaviour measured	Recording	Training	Observation and Setting	Reliability	Validity
Dean[223] (1993) UK	Quality of Interaction Schedule (QUIS)	Number and quality of interactions between residents and others. Coded as: Positive social, positive care, neutral, negative protective and negative restrictive.	Hand recorded	Not stated.	15 minute observations across the daytime period (9am-6pm). Nursing homes.	Kappa 0.60-0.91	Increases in the quantity and quality of activities and interactions experienced by residents were associated with improvements in ratings of resident's cognitive impairment, observed depression and functional capacities.
Lann-Wolcott[230], (2011), US. Grosch[231] (2008), US	Person-centred behaviour instrument (PCBI)	Interactions between staff and residents. 11 verbal categories (eg shows approval, 'back-channel responses' (not explained in paper), giving choice); 8 nonverbal categories (eg resident directed eye gaze, adjusting to residents pace, proximity)	Video recorded	Training stated as given, but no details of how.	Coding every 2mins or 30 seconds (depending on study) whether or not target behaviour observed. Nursing homes.	Kappa>=0.8 IRR 0.86	Face validity as behaviours coded identified in a prior study of skilled certified nursing assistants and corresponded to many of the items in the literature on nurse-patient and nurse-resident interactions. Concurrent validity between the PBCI and the Global Behaviour Scale (Grosch, 2008) of r=0.49, p<0.02. Discussion states that more validation of the tool is needed. Discusses validating the tool against the Dementia Care Mapping Well-Being/Ill-being

							scores.
Author, year, country	**Name of instrument**	**Behaviour measured**	**Recording**	**Training**	**Observation and Setting**	**Reliability**	**Validity**
Norman[229] (1994), UK	Quality Assessment Project (QAP)	11 types of activity (communication, elimination, eating etc) and scored as appropriately and adequately, appropriately and inadequately, not appropriately but adequately, inappropriately and inadequately.	Hand recorded	No details given.	Observations between 1 and 3 x 4 hour periods. Activities of patients sampled at 6 minute intervals. Hospital wards.	IRR 78-88%	Concurrent validity shown by the mean ratio percentage agreement with continuous observations over the same period was 75%.
Kovach[197] (1997) US	Systematic Behavioural Mapping (no specific name).	Types of resident behaviour (social, passive, active, other) and staff behaviour (resident orientated, staff orientated, task orientated).	Hand recorded	No details given.	Every 20 minutes between 07:00 and 19:00 an observer walked through and recorded on a checklist resident and staff behaviours. Nursing homes and dementia care units.	IRR calculated as percentage agreement – 96% for behavioural assessments.	Content validity – three specialists in dementia care reviewed the checklist for clarity and ability to capture the range of behaviours in which residents and staff commonly engaged.

Appendix 3: Example of Nottingham CTU Weekly Sub-Sample Email

Attempting to select 8 participants from between 01/08/2011 and 07/08/2011 (inclusive) who were randomised to intervention arm (from 8 participants allocated to this arm during this period)
1st choice =1452
2st choice =182
3rd choice =1453
4th choice =1449
5th choice =1450
6th choice =1455
7th choice =181
8th choice =183

Attempting to select 8 participants from between 01/08/2011 and 07/08/2011 (inclusive) who were randomised to control arm (from 5 participants allocated to this arm during this period)
1st choice =179
2st choice =1451
3rd choice =178
4th choice =180
5th choice =1454
6th choice =N/A
7th choice =N/A
8th choice =N/A

Note: numbers shown above are the participant's randomisation numbers
Date/time of sub-sampling : 08/08/2011 07:00:03

This is an automated email, please do not reply to this email. Should you require any assistance please contact the CTU IT manager
For more information about the University of Nottingham's Clinical Trials Unit please visit http://ctu.nottingham.ac.uk

Appendix 4: DCM Data Collection Sheets

Observation Date: **Patient No:** **Pt initials**

Time	Min staff	Max staff	Min visitors	Max visitors	Social X^n
	DCM	**Patient interactions**		**General Observations**	
BCC					
ME					
PE/PD					
Buzzer					
Tel					
IV					
Bed					
Radio					
BP					
Other					
Shouts					

SN senior nurse, N staff nurse, MHN mental health nurse, StN student nurse, AN auxiliary nurse, OT occupational therapist, PT physiotherapist, DRcon consultant, DR doctor, StDR student doctors, D domestic, SALT speech and language therapist, DIET dietician, SW social worker, CH chaplain, P Porter, R receptionist, V visitor, CV co-visitor, DC discharge coordinator, CP co-patient. SpN specialist nurse, Pb Phlebotomist, AgAN agency auxiliary, AgN agency nurse.

Appendix 5: Power calculation and sample size estimates

This sample size calculation was delegated to Lucy Bradshaw, the Medical Crises in Older People Programme grant statistician. It was based on the primary outcome measure of percentage time in positive mood. Two calculations were done, one based on the assumption the data would be normally distributed, the other based on the assumption the data would be non-parametric.

The sample size for this study is based on the feasibility of researchers conducting the dementia care mapping on the two wards. Each observation takes 6 hours and it is anticipated that a researcher will have available time for 1 observation of Dementia Care Mapping each week. It is anticipated that 2 researchers will be available each week for the remaining randomised controlled trial of the MMHU study period of 44 weeks so it is feasible that the Dementia Care Mapping observations can be conducted on 88 patients (44 from each ward).

The primary outcome is the proportion of time each patient spends in positive mood or engagement state. It is expected that the distribution of the proportion of time that each patient spends in positive mood or engagement state will be left (or negatively skewed) with most patients spending the majority of time in positive mood but with some patients having a very small amount of time in positive mood so a non-parametric test will be the most appropriate method of analysing the data. The Mann-Whitney test assesses the degree of overlap between the distributions of a continuous outcome variable in two groups. Under the null hypothesis that there is no difference between the time spent in positive engagement, the probability that an observation from the standard ward exceeds an observation from the MMHU ward is 0.5 because the ward type has no discriminatory ability for the proportion of time spent in positive mood. If the time spent in positive mood of all patients on the MMHU ward exceeds that of the patients on the

standard ward, this probability would be 0 as group has perfect discriminatory ability for the proportion of time spent in positive mood. Using a Mann-Whitney test to analyse the data with 44 patients in each group, there is 80% power to detect the probability of 0.32 (or less) that a patient on the standard ward spends more time in positive mood than a patient on the MMHU ward (calculated using nQuery software).

Using pilot data collected on 15 patients, the standard deviation of the proportion of time spent in positive mood or engagement was 0.17. If the proportion of time spent in positive mood or engagement is assumed to be normally distributed with a standard deviation of 0.17, the probability of 0.32 that a patient on the standard care ward spends more time in positive mood than a patient on the MMHU ward equates to a difference in mean proportion of time spent in positive mood of 0.11 between the two groups.

Justification based on a t-test

The sample size for this study is based on the feasibility of researchers conducting the dementia care mapping on the two wards. Each observation takes 6 hours and it is anticipated that a researcher will have available time for 1 observation of the Dementia Care Mapping each week. It is anticipated that 2 researchers will be available each week for the remaining study period of 44 weeks so it is feasible that the Dementia Care Mapping observations can be conducted on 88 patients (44 from each ward).

The primary outcome is the proportion of time each patient spends in positive mood or engagement state. Using pilot data on 15 patients gathered to assess the feasibility of Dementia care mapping, the mean proportion of time spent in positive mood or engagement was 0.72 with a standard deviation of 0.17. Using this data, a sample size of 44 patients in each group has 80% power to detect a difference in mean proportion of time spent in positive mood or engagement of 0.105 (for example a mean of 0.835 for patients on the MMHU ward and a mean of 0.72 for patients on the standard ward) or 90% power to detect a difference in means of 0.12 using a two-sided independent

t-test. There is a possibility that the proportion of positive time spent in positive engagement will be non-normally distributed in which case a non-parametric test will be used to analyse the data.

The table below shows the difference in mean proportion of time spent in positive engagement between the two groups that can be detected with 80% or 90% power with 44 patients in each group if the standard deviation is greater than observed in the pilot study.

Standard Deviation	80% power	90% power
0.17	0.105	0.120
0.20	0.120	0.140
0.22	0.135	0.155
0.25	0.150	0.175

Simulation Exercise

A simulation exercise was conducted to examine how robust the power calculations for the study are to deviations from the normal distribution. The simulation proceeded as follows:

1. Simulate 10,000 observations from a normal distribution for the proportion of time spent in positive mood on the MMHU ward and 10,000 observations from a normal distribution for the proportion of time spent in positive mood on the standard ward with standard deviation 0.2. The means of the normal distribution were varied to simulate samples under a number of different scenarios for the proportion of time spent in positive mood on the two wards.

2. Retain the simulated observations which lie between 0 and 1 (the range of values for the proportion of time in positive mood). This creates skewed distributions which may be more realistic than assuming that the proportion of time in positive mood is normally distributed.

3. Randomly sample a dataset of size 44 from the simulated data for the MMHU ward and the also from the simulated data for the standard ward. Test for a difference in the proportion of time spent in positive mood using a Mann-Whitney test.

4. Repeat step 3 a large number of times, 4000 in this simulation exercise. Calculate the power of the Mann-Whitney test to detect the difference in the datasets observed at step 2 by the proportion of p-values that are less than 0.05.

In this way, data is simulated from the MMHU ward and standard care ward at step 2, where the difference between the two samples is known. This allows the power of the Mann-Whitney test to detect the known differences to be calculated with a sample size of 44 in each group.

The table below shows results for the simulation under a number of different scenarios.

Note for the first 5 simulations, the proportion of the sample with their proportion of time spent in positive mood greater than 0.90 was around 24% for the MMHU ward and 11% for the standard ward.

| | | Proportion of time in positive mood from step 2 | | | | Power (as calculated in steps 3 and 4) |
	Ward	Median (IQR)	Proportion of sample > 0.90	Difference in Medians	P(stan > mmhu)*	
1	MMHU	0.805 (0.695 – 0.898)		0.102	0.334	78.8%
	Standard	0.703 (0.578 – 0.815)				
2	MMHU	0.803 (0.688 – 0.899)		0.112	0.326	82.2%
	Standard	0.691 (0.560 – 0.812)				

3	MMHU	0.804 (0.692 – 0.899)		0.110	0.330	79.9%
	Standard	0.694 (0.566 – 0.814)				
4	MMHU	0.810 (0.698 – 0.900)		0.113	0.325	83.3%
	Standard	0.697 (0.570 – 0.818)				
5	MMHU	0.810 (0.699 – 0.904)		0.103	0.333	77.5%
	Standard	0.707 (0.579 – 0.823)				
6	MMHU	0.825 (0.718 – 0.912)	28.1%	0.102	0.332	79.0%
	Standard	0.723 (0.599 – 0.835)	13.1%			
7	MMHU	0.825 (0.717 – 0.913)	30.0%	0.102	0.330	81.8%
	Standard	0.723 (0.596 – 0.836)	13.1%			
8	MMHU	0.848 (0.743 – 0.925)	33.1%	0.103	0.326	83.4%
	Standard	0.745 (0.622 – 0.855)	15.5%			
9	MMHU	0.843 (0.740 – 0.924)	32.8%	0.096	0.336	76.7%
	Standard	0.747 (0.627 – 0.857)	16.5%			

* P(stan > mmhu) is the probability that an observation on the proportion of time spent in positive mood from standard ward is greater than an observation from the MMHU ward.

Appendix 6: Publications, Conference Presentations, Prizes, Scientific Committees and Grants

Peer Reviewed Publications

Goldberg SE, Whittamore KH, Harwood RH, Bradshaw LE, Gladman JRF, Jones R, On behalf of the Medical Crises in Older People Study Group. *Age Ageing* 2012; doi: 10.1093/ageing/afr106

Harwood RH, **Goldberg SE**, Whittamore KH, Russell C, Gladman JRF, Jones RG, Porock D, Lewis SA, Bradshaw LE, Elliott RA and Medical Crises in Older People Study Group (mcop) *Trials* 2011; 12:123

Gladman, J, **Goldberg S**, Harwood R, Whittamore, K The prevalence of mental health problems amongst older adults admitted as an emergency to a general hospital. *Ageing Clinical and Experimental Research* 2011; 23 (S1): 117 [S Goldberg first author, platform presentation at the IAGG conference, Bologna, May 2011]

Goldberg S, Harwood R, Whittamore K, Gladman J. Recruiting older patients with mental health problems on an acute medical ward to a cohort study. *Age Ageing* 2001; 40 (Suppl 1): i75 http://dx.doi.org/10.1093/ageing/afr002 [poster presentation]

Russell C, Edwards G, Porock D, **Goldberg SE**, Harwood RH Implementation of 'About Me':- promoting person-centred care on an acute medical ward for older people with confusion. *Age Ageing* 2011; 40(Suppl 1):i11. http://dx.doi.org/10.1093/ageing/afr002 [poster presentation]

Goldberg S, Harwood R, Jones R, Logan P, Gladman J and the MCOP Study Group. Screening for mental health problems on acute hospital wards. Age Ageing 2010; 39 (2): ii85 http://ageing.oxfordjournals.org/content/39/suppl 2/ii1.full.pdf [poster presentation]

Other Publications

Goldberg, S Why nurses fail to care properly for elderly patients - letter. *The Independent* 17 October 2011 p16

Goldberg, S Nursing care needs more than kindness - letter. *The Guardian* 17 October 2011 p31

Goldberg S, Harwood RH, Gladman JRF. Mental health problems on hospital medical wards: a listening event. *Medical Crises in Older People Discussion Paper* series 7. 2011. http://www.nottingham.ac.uk/mcop/documents/papers/issue7-mcop-issn2044-4230.pdf

Gladman JRF, Jurgens F, Harwood R, **Goldberg S**, Logan P. Better mental health in general hospitals. *Medical Crises in Older People Discussion Paper* series 3. 2010 http://www.nottingham.ac.uk/mcop/documents/papers/issue3-mcop-issn2044-4230.pdf

Gladman JRF, Logan P, Robbins I, Gordon A, **Goldberg S.** Health Care Services for UK *Care Homes Medical Crises in Older People Discussion Paper* series 2. 2010 http://www.nottingham.ac.uk/mcop/documents/papers/issue2-mcop-issn2044-4230.pdf

Goldberg SE Practice comment: Better training is needed to provide the support that people with dementia and their carers need. *Nursing Times.* 2009. http://www.nursingtimes.net/whats-new-in-nursing/specialists/older-people/better-training-is-needed-to-provide-the-support-that-people-with-dementia-and-their-carers-need/5004910.article

Oral Presentations

Goldberg, S The patient experience of care on a medical and mental health unit compared to standard care. [Concurrent presentation at the RCN International Research Conference, London, April 2012]

Goldberg S The prevalence of mental health problems amongst older adults admitted as an emergency to a general hospital. [Concurrent presentation at the RCN International Research Conference, Harrogate, April 2011]

Gladman, J, **Goldberg S**, Harwood R, Whittamore, K The prevalence of mental health problems amongst older adults admitted as an emergency to a general hospital. *Ageing Clinical and Experimental Research* 2011; 23 (S1): 117 [S Goldberg first author, platform presentation at the IAGG conference, Bologna, May 2011]

Goldberg, S The East Midlands Strategic Health Authority "Improving Dementia Care" conference Friday 4th November 2011.

Scientific Committees

Early career researcher on the scientific committee of the RCN 2012 Annual International Nursing Research Conference

Prizes
Winner of the Eva Huggins prize for best nurse poster British Geriatrics Society November 2009

Grants

NIHR Research for Patients Benefit Grant. PB-PG-0110-21229 In a general hospital are older people with cognitive impairment managed better in a specialist unit? (£248k; **Goldberg** (PI), Gladman, Harwood, Pollock, Schneider, Porock).

Nottingham University Hospital NHS Pump Priming fund. Continence problems amongst older people admitted to hospital with dementia: features and natural history. (£9k; **Goldberg** (PI)).

Appendix 7: List of Abbreviations

AMU	Acute Medical Admissions Unit
BCC	Behaviour Category Codes
CI	Confidence Interval
CQC	Care Quality Commission
DRS	Delirium Rating Scale
ED	Emergency Department
IQR	Inter-Quartile Range
NICE	National Institute for Clinical Excellence
NHS	National Health Service
MEWS	Modified Early Warning Score
ME	Mood and engagement scores
MMHU	Medical and Mental Health Unit
MMSE	Mini-Mental State Examination
NHS	National Health Service
NIHR	National Institute for Health Research
NPI	Neuropsychiatric Inventory
PALS	Patient Advisory Liaison Service
PCT	Primary Care Trust
PD	Personal detractor
PE	Personal enhancer
PIE	Patient Interactions and Environment
QALY	Quality Adjusted Life Year
RCN	Royal college of nursing
RfPB	Research for Patient Benefits
TEAM	Trial of an Elderly Acute Medical and Mental Unit
UK	United Kingdom

Appendix 8: Patient Short Information Sheet

**Study of hospital care for older people with confusion
Summary information**

We would like to invite you to take part in a research study.

We have developed a ward at QMC for older people whose problems include being forgetful or confused. We want to find out if this new ward really is better for patients and their families, compared with other hospital wards.

If you take part:
- We will ask about your health now, and how it affects you.
- We will also ask family members or carers about their health.
- We will watch some day-to-day care on the wards.
- We would like to see your health and care records.
- We will ask family members if they were satisfied with your care.
- We will visit you at home in 3 months time to ask about your health again.
- We may ask to do an interview with you or a family member about how you found it in hospital.

You do not have to take part, if you don't want to.
Please ask if you want more time to make up your mind, or if you need to know more. You can stop taking part at any time, just by telling us.

There should be no risks from the study.
Your hospital treatment will stay the same. In the study we only ask questions and watch what happens on wards.

The independent Nottingham Research Ethics Committee has looked at the study and is happy to let us do it.

Please let us know if you are worried about this study. Ask your researcher, or you can phone Prof John Gladman on 0115 823 0242.

Any information we collect will be kept strictly private.
We will tell other hospitals what we find at medical meetings and by writing articles in medical journals. But we never mention any names.

Division of Rehabilitation and Ageing, Medical School, Queens Medical Centre, Nottingham NG7 2UH. Email john.gladman@nottingham.ac.uk

Evaluation of hospital care for older people with confusion

Patient Participant Information Sheet

We would like to invite you to take part in a research study being done by the Hospital NHS Trust and Nottingham University. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our research team will go through the information sheet with you and answer any questions you have. Please ask the researcher if there is anything that is not clear.

What is the purpose of the study?

We have developed a Medical and Mental Health Unit (MMHU) at Queens Medical Centre. This unit specialises in the care of older patients who may have a medical problem who are also forgetful or confused. We do not know whether the care provided by the MMHU is better than that provided by other areas of the hospital, or whether it benefits some types of patients more than others. There are not enough beds on the MMHU to care for all forgetful or confused older patients in the hospital. We are comparing care and outcomes for patients managed on different types of ward.

Why is the study being done?

We realise that older people with confusion can be distressed in hospital, and sometimes patients' and carers' experiences of being in hospital are not good. However, no-one really knows the best way to provide care for such patients. The National Institute for Health Research, part of the Department of Health, has commissioned us to study the problems of confused older people in hospital, and then test different ways of providing their care.

Why have I been chosen?

We are asking patients to take part if they are sixty-five years or older, were admitted to hospital as an emergency, and at the time of admission were confused.

What will happen if I take part in this research study?

We want to find out what sort of problems there are, and how commonly they occur.

- We will ask questions about your health and how it affects you.
- We may need to ask family members or carers to fill in some of the details if you are unable.
- We want to know about the effect of ill-health on family members, carers and others, so we would like to ask them questions too.
- We will have some specially-trained nurses watching what happens on wards during everyday care.
- We will telephone a family member or carer 1-3 weeks after you are discharged to ask how satisfied they were with aspects of your hospital care.
- We would like to find out how things go over the next 3 months, by visiting you at home to answer questions about your health again (or you could come to the hospital for this if you preferred).
- We would like permission to look at your health and social services records so we can see what treatments you had, and which services you used.
- We will invite some patients to do an in-depth interview about the care you are receiving in hospital. The interview will be tape recorded. Everything you tell us in the interview will be confidential.
- We will notify your hospital consultant and your GP of your participation in the study.
- If we find anything urgent and serious your ward team doesn't know about already we will let them know.

Do I have to take part? Can I stop being in the study?

You do not have to take part. Because this is a research study we must ask your agreement if you do. We will ask you to sign a consent form to say you agree. If you choose not to take part, this will not affect your routine care in any way. If

you agree to take part, you can withdraw at any time without telling us why (if you don't want to). But we need to talk to as broad a spectrum of people as possible so we understand the problems fully, and can apply them here and in other hospitals elsewhere. So we would be very grateful if you would agree.

If you are not feeling up to it just now we can come back over the next day or 2, but we need to start as soon as possible after admission. We will try to make collecting the information as easy as possible.

If you need time to make your decision please just ask. You may like to discuss it with your family or friends. If you have any questions, you can ask your researcher for more explanation.

Are there any risks from being in the study?

In this study we are just collecting information and watching what happens to people like you in hospital and afterwards, so there should be no risks. All we need from you is the time to complete the interviews and assessments. Some of the issues we discuss may be upsetting, but many people find talking about their experiences helpful. Our researchers are experienced in dealing with these sorts of problems.

Will my medical information be kept private?

All information resulting from participants taking part in the study will be stored in a locked filing cabinet and in a computer. This will be treated confidentially. All information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Will I be paid to take part in this study?

No, you will not be paid for taking part in this study.

Can I complain about the study?

If there are any problems please let us know. You can discuss any matters with the following person: Professor

John Gladman tel 0115 823 0242. We can put you in touch with an independent advisor if you are concerned about something to do with the research that you would rather not discuss directly with the researchers. Alternatively, contact the Patient Advice and Liaison Service (PALS) on 0115 875 4655.

What will happen to the results of the research study?

It will take three years to complete the study. The findings will be analysed by the research team in the University, then be published in clinical journals and used to develop new local services. Direct quotes may be used in the research publication but you will not be identifiable from these. You will not be identified in any report or publication.

Who is organising and funding the research?

This research is funded by the National Institute of Health Research. This is the part of the NHS responsible for funding clinical research.

The Division of Rehabilitation and Ageing at the University of Nottingham is organising the research, working closely in partnership with the Nottingham University Hospitals NHS Trust.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Nottingham Research Ethics Committee.

Contact for further information

If you have any further questions about this study please do not hesitate to contact:
Professor John Gladman,
Division of Rehabilitation and Ageing,
Medical School, Queens Medical Centre,
Nottingham NG7 2UH

Telephone 0115 823 0242
Email john.gladman@nottingham.ac.uk

Thank you

Study ID ....

Date	
Patient Initials	
Interview completed by:	

Questionnaire completed by:

Please tick one box

The patient participant ……………..……… ☐
Jointly by the patient participant and carer ☐
Someone else:
Who? husband or wife ………………………………….. ☐
another relative (please specify in the box below)…... ☐

a friend………………………………………………… ☐
a paid carer………………………………………………… ☐
any other (please specify in the box below)……....... ☐

A. Living arrangements. If someone is completing the questionnaire on behalf of the patient participant, please give THE ANSWERS THE PATIENT PARTICIPANT WOULD GIVE if they were able.

1. Is the patient participant currently

Please tick one box

married or have a partner?…...……… ☐
divorced or separated?…….….……… ☐
widowed?……………………………….... ☐
never married?…………………….…….. ☐

2. Does the patient participant live permanently:

Please tick one box

alone?………………………………………………….……............... ☐
with a spouse, other relative, friend or companion?…….…................ ☐
in a care home (with nursing care)?………….....………………………. ☐
in a care home (without nursing)?………....…………………………… ☐

3. Was the patient participant admitted from respite care?
(temporary care home resident) Yes…………………… ☐
No…………………… ☐

Complete for main earner in the family			
4.	What was the best job you or your spouse ever had? *(If pressed, best salary)* If dual income family, the better job of the two. Record job description and refer to list	Manager / administrator	1
		Professional	2
		Associate professional	3
		Clerical worker / Secretary	4
		Skilled labourer	5
		Services / Sales	6
		Factory worker	7
		Other: _____	8
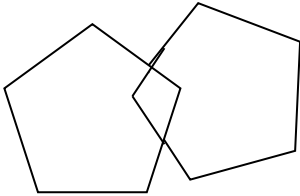
Sections to be completed by direct interview with the participant or if participant unable to answer through informant.

B. Cognition: Will you do a memory test for me?

[MMSE]

ORIENTATION	
What is the year, season, month, date, day (write down date response)	**/ 5**
Where are we: country, county, town, hospital, ward	**/5**
MEMORY REGISTRATION	
Examiner names 3 objects (apple, table, penny) Patient asked to repeat the 3 names – score one for each correct answer Then patient to learn 3 names (i.e. repeat until correct)	**/3**
ATTENTION AND CALCULATION	
Subtract 7 from 100, then repeat from result etc. Stop after 5. 100 93 86 79 72 65 (Alternatively, spell "world" backwards. D L R O W)	**/5**
RECALL	
Ask for 3 objects learnt earlier	**/3**
LANGUAGE	
Name a pencil and watch	**/2**
Repeat "No, ifs, ands, or buts"	**/1**
Give a 3-stage command. Score one point for each correct stage. (e.g. "take the paper in your right hand, fold it in half and put it on the table")	**/3**
Ask the patient to read and obey a written command on a piece of paper, stating: "close your eyes".	**/1**
Ask the patient to write a sentence. Score if it is sensible and has a subject and a verb.	**/1**

COPYING	
Ask the patient to copy a pair of intersecting pentagons	**/1**
TOTAL SCORE	**/30**

CLOSE YOUR EYES

Large print version used for interview ☐

Hearing aid used for interview ☐

[DRS] 1. Sleep wake cycle disturbance.

Rate sleep-wake pattern using all sources of information, including from family, caregivers, nurses' reports, and patient. Try to distinguish sleep from resting with eyes closed

score   *Please tick one box*

0   Not present ……………………………………………………………………………… ☐
1   Mild sleep continuity disturbance at night or occasional drowsiness during the day .. ☐
2   Moderate disorganisation of sleep-wake cycle (e.g. falling asleep during conversations, napping during the day or several brief awakenings during the night with confusion/behavioural changes or very little night time sleep) ……. …………… ☐
3   Severe disruption of sleep wake cycle (e.g. day-night reversal of sleep wake cycle, or severe circadian fragmentation with multiple periods of sleep and wakefulness or severe sleeplessness) ………………………………….. …………………………. ☐

[DRS] 2. Perceptual disturbances and hallucinations.
Illusions and hallucinations can be of any sensory modality. Misperceptions are "simple" if they are uncomplicated, such as a sound, noise, colour, spot, or flashes and "complex" if they are multidimensional, such as voices, music, people, animals, or scenes. Rate if reported by patient or caregiver, or inferred by observation

score   *Please tick one box*

0   Not present ……………………………………………………………………………. ☐
1   Mild perceptual disturbances (e.g., feelings of derealization or depersonalization; or patient may not be able to discriminate dreams from reality) ……………………… ☐
2   Illusions present ……………………………………………………………….. ☐
3   Hallucinations present ……………………………………....……………………. ☐

[DRS] 3. Delusions.
Delusions can be of any type, but are most often persecutory. Rate if reported by patient, family or caregiver. Rate as delusional if ideas are unlikely to be true yet are believed by the patient who cannot be dissuaded by logic. Delusional ideas cannot be explained otherwise by the patient's usual cultural or religious background.

score   *Please tick one box*

0   Not present ………………….…………………....……………………………………… ☐
1   Mildly suspicious, hypervigitant, or preoccupied ………………………………… ☐
2   Unusual or overvalued ideation that does not reach delusional proportions or could be plausible ………………………….…………………………………. ☐
3   Delusional …………………….…………....…………………………………… ☐

[DRS] 4. Lability of affect (do mood and emotions vary, are they under control and appropriate?).
Rate the patient's affect as the outward presentation of emotions and not as a description of what the patient feels.

score   *Please tick one box*

0   Not present ………………….……………………....…………………………….. ☐
1   Affect somewhat altered or incongruent to situation; changes over the course of hours; emotions are mostly under self-control …………………….. ☐
2   Affect is often inappropriate to the situation and intermittently changes over the course of minutes; emotions are not consistently under self-control, though they respond to redirection by others ……………………………………………… ☐
3   Severe and consistent disinhibition of emotions; affect changes rapidly, is inapp*r*opriate to context, and does not respond to redirection by others …. ☐

[DRS] 5. Language.
Rate abnormalities of spoken, written or sign language that cannot be otherwise attributed to dialect or stuttering. Assess fluency, grammar, comprehension, semantic content and naming. Test comprehension and naming nonverbally if necessary by having patient follow commands or point.

score   *Please tick one box*

0	Normal language …………………………………………..………………………….	☐
1	Mild impairment including word-finding difficulty or problems with naming or fluency …	☐
2	Moderate impairment including comprehension difficulties or deficits in meaningful communication (semantic content) ………………………………………………………..	☐
3	Severe impairment including nonsensical semantic content, word salad, muteness, or severely reduced comprehension …………………………………………………………..	☐

[DRS] 6. Thought process abnormalities *(do thoughts flow logically one to the next, coherence of thought).* Rate abnormalities of thinking processes based on verbal or written output. If a patient does not speak or write, do not rate this item.

score   *Please tick one box*

0	Normal thought processes ………………………………..………...……………..	☐
1	Tangential or circumstantial ………………………………………………………	☐
2	Associations loosely connected occasionally, but largely comprehensible ……..	☐
3	Associations loosely connected most of the time …………………………..……..	☐
	Patient does not speak or write	☐

[DRS] 7. Motor agitation.
Rate by observation, including from other sources of observation such as by visitors, family and clinical staff. Do not include dyskinesia, tics, or chorea.

score   *Please tick one box*

0	No restlessness or agitation …………………………………………....….....	☐
1	Mild restlessness of gross motor movements or mild fidgetiness	☐
2	Moderate motor agitation including dramatic movements of the extremities, pacing, fidgeting, removing intravenous lines, etc	☐
3	Severe motor agitation, such as combativeness or a need for restraints or seclusion	☐

[DRS] 8. Motor retardation. `
Rate movement by direct observation or from other sources of observation such as family, visitors, or clinical staff. Do not rate components of retardation that are caused by parkinsonian symptoms. Do not rate drowsiness or sleep.

score   *Please tick one box*

0	No slowness of voluntary movements …………….………………….…..….....	☐
1	Mildly reduced frequency, spontaneity or speed of motor movements, to the degree that may interfere somewhat with the assessment.	☐
2	Moderately reduced frequency, spontaneity or speed of motor movements to the degree that it interferes with participation in activities or self-care	☐
3	Severe motor retardation with few spontaneous movements.………….......	☐

[DRS] 9. Orientation. (*Note specific, and liberal, definition of orientation to person*)

Disorientation to person means not recognizing familiar persons and may be intact even if the person has naming difficulty but recognizes the person. Disorientation to person is most severe when one doesn't know one's own identity and is rare. Disorientation to person usually occurs after disorientation to time and/or place. Patients who cannot speak can be given a visual or auditory presentation of multiple choice answers. Allow patient to be wrong by up to 7 days instead of 2 days for patients hospitalized more than 3 weeks.

Score   *Please tick one box*

0	Oriented to person, place and time ……………………………….………………..	☐
1	Disoriented to time (e.g., by more than 2 days or wrong month or wrong year) or to place (e.g., name of building, city, state), but not both ……………………………	☐
2	Disoriented to time and place	☐

3	Disoriented to person	☐

[DRS] 10. Attention.

Attention can be assessed during the interview (e.g., verbal perseverations, distractibility, and difficulty with set shifting) and /or through use of specific tests, e.g., digit span. Patients with sensory deficits or who are intubated or whose hand movements are constrained should be tested using an alternate modality besides writing.

Score   *Please tick one box*

0   Alert and attentive …………………………………..………………….....….…………..   ☐

1   Mildly distractible or mild difficulty sustaining attention, but able to refocus with cueing. On formal testing makes only minor errors and is not significantly slow in responses ……………………………………………………………………………………..   ☐

2   Moderate inattention with difficulty focusing and sustaining attention. On formal testing, makes numerous errors and either requires prodding to focus or finish the task……   ☐

3   Severe difficulty focusing and/or sustaining attention, with many incorrect or incomplete responses or inability to follow instructions. Distractible by other noises or events in the environment …………………………………………………………..   ☐

[DRS] 11. Short-term memory.

Defined as recall of information (e.g. 3 items presented either verbally or visually) after a delay of about 2 to 3 minutes. When formally tested, information must be registered adequately before recall is tested. The number of trials to register as well as effect of cueing can be noted on scoresheet. Patient should not be allowed to rehearse during the delay period and should be distracted during that time. Patient may speak or nonverbally communicate to the examiner the identity of the correct items. Short-term deficits noticed during the course of the interview can be used also.

Score   *Please tick one box*

0   Short-term memory intact   ☐

1   Recalls 2/3 items; maybe able to recall third item after category cueing   ☐

2   Recalls 1/3 items; may be able to recall other items after category cueing   ☐

3   Recalls 0/3 items ……………………………….……………….......   ☐

[DRS] 12. Long-term memory [DRS]. *(Try current news items, children, medical history)*

Can be assessed formally or through interviewing for recall of past personal (e.g. past medical history or information or experiences that can be corroborated from another source) or general information that is culturally relevant. When formally tested, use a verbal and/or visual modality for 3 items that are adequately registered and recalled after at least 5 minutes. The patient should not be allowed to rehearse during the delay period during formal testing. Make allowances for patients with less than 8 years of education or who are mentally retarded regarding general information questions. Rating of the severity of deficits may involve a judgment about all the ways long-term memory is assessed, including recent and/or remote long-term memory ability informally tested during the interview as well as any formal testing of recent long-term memory using 3 items.

score   *Please tick one box*

0   No significant long-term memory deficits …………………..…………………......…....   ☐

1   Recalls 2 /3 items and/ or has minor difficulty recalling details of other long-term information ………………………………………………………………………………….   ☐

2   Recalls 1/3 items and/ or has moderate difficulty recalling other long-term information   ☐

3   Recalls 0/3 items and/or has severe difficulty recalling other long-term information. ………………………………………………………………………………   ☐

[DRS] 13. Visuospatial ability *(use intersecting pentagons, and reports of navigation on ward or at home)* Assess informally and formally. Consider patient's difficulty navigating one's way around living areas or environment (e.g. getting lost). Test formally by drawing or copying a design, by arranging puzzle pieces, or by drawing a map and identifying major cities, etc. Take into account any visual impairments that may affect performance

Score		Please tick one box
0	No impairment ……………………………..………………..……………………....	☐
1	Mild impairment such that overall design and most details or pieces are correct; and/or little difficulty navigating in his/her surroundings ………………………….	☐
2	Moderate impairment with distorted appreciation of overall design and/or several errors of details or pieces; and/or needing repeated redirection to keep from getting lost in a newer environment despite, trouble locating familiar objects in immediate environment ………………………………………………………	☐
3	Severe impairment on formal testing; and/or repeated wandering or getting lost in environment …………………………………………………...………………………	☐

[DRS] 14. Temporal onset of symptoms *(Rate change in mental state or behaviour).*
Rate the acuteness of onset of the initial symptoms of the disorder or episode being currently assessed, not their total duration. Distinguish the onset of symptoms attributable to delirium when it occurs concurrently with a different preexisting psychiatric disorder. For example, if a patient with major depression is rated during a delirium episode due to an overdose, then rate the onset of the delirium symptoms.

score		Please tick one box
0	No significant change from usual or longstanding baseline behaviour ...	☐
1	Gradual onset of symptoms, occurring over a period of several weeks to a month	☐
2	Acute change in behaviour or personality occurring over days to a week	☐
3	Abrupt change in behaviour occurring over a period of several hours to a day …	☐

[DRS] 15. Fluctuation of symptom severity. *(Apply to any mental or psychological symptoms or behaviour)*
Rate the waxing and waning of an individual or cluster of symptom(s) over the time frame being rated. Usually applies to cognition, affect, intensity of hallucinations, thought disorder, language disturbance. Take into consideration that perceptual disturbances usually occur intermittently, but might cluster in period of greater intensity when other symptoms fluctuate in severity,

score		Please tick one box
0	No symptom fluctuation	☐
1	Symptom intensity fluctuates in severity over hours	☐
2	Symptom intensity fluctuates in severity over minutes	☐

[DRS] 16. Physical disorder *(any drug, infection, metabolic or brain disorder or other medical problem).*
Rate the degree to which a physiological, medical or pharmacological problem can be specifically attributed to have caused the symptoms being assessed. Many patients have such problems but they may or may not have causal relationship to the symptoms being rated.

score		Please tick one box
0	None present or active.………………………………..……………………....…....	☐
1	Presence of any physical disorder that might affect mental state	☐
2	Drug, infection, metabolic disorder, CNS lesion or other medical problem that specifically can be implicated in causing the altered behaviour or mental state	☐

D. EQ5D This set of questions about how YOUR health is at the moment. Which statement best describes your own health state today? (Proxy replies are acceptable) Please record most believable answer
(ie if participant in bed unable to walk and they say they have no problem walking then record as confined to bed).
If answer lies between two mark as more severe (ie not confined to bed, but can't walk, put as confined to bed).
Ask for state on day of the interview (ie have you felt pain today, are you anxious or depressed today.)

Questions answered by:	
Patient	☐
Proxy	☐
Patient and Proxy	☐

1. Mobility

	Patient	Proxy
I am confined to bed………………………………………………	☐	☐
I have some problems in walking about…..…………	☐	☐
I have no problems walking about……..……………	☐	☐

2. Self care

	Patient	Proxy
I am unable to wash or dress myself……………………	☐	☐
I have some problems in washing or dressing……………	☐	☐
I have no-problems with looking after myself…..………	☐	☐

3. Usual activities (e.g. housework, leisure, family)

	Patient	Proxy
I am unable to perform my usual activities.……………	☐	☐
I have some problems performing my usual activities	☐	☐
I have no problems performing my usual activities.…	☐	☐

4. Pain / Discomfort

	Patient	Proxy
I have no pain or discomfort……………………….………	☐	☐
I have moderate pain or discomfort……………….…	☐	☐
I have extreme pain or discomfort……………….…..	☐	☐

5. Anxiety / Depression

	Patient	Proxy
I am not anxious or depressed……………….……………	☐	☐
I am moderately anxious or depressed…………..………	☐	☐
I am extremely anxious or depressed………..…………	☐	☐

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E. Prior activities of daily living. Please score what the patient participant actually did prior to the current illness, or 3 months ago if current illness longer than this. **If answer falls between two, score down ie more dependent.**.

How do they manage with eating?	Unable	0	
	Needs help cutting, spreading butter etc.	1	
	Independent (food provided in reach)	2	
How do they manage with grooming?	Needs help with personal care	0	
	Independent face/hair/teeth/shaving (implements provided)	1	
How do they manage with dressing?	Dependent	0	
	Needs help but can do about half unaided	1	
	Independent (including buttons, zips, laces etc.)	2	
How do they manage with bathing?	Dependent	0	
	Independent (or in shower)	1	
How do they manage using the toilet?	Dependent	0	
	Needs some help but can do something alone	1	
	Independent (on and off, dressing, wiping)	2	
How do they manage with their bladder?	Incontinent or catheterised and unable to manage	0	
	Occasional accident (max once per 24 hours)	1	
	Continent (for over 7 days)	2	
How do they manage with their bowels?	Incontinent (or needs to be given enema)	0	
	Occasional accident (once per week)	1	
	Continent	2	
How do they manage with transferring?	Unable - no sitting balance	0	
	Major help (one or two people, physical) can sit	1	
	Minor help (verbal or physical)	2	
	Independent	3	
How do they manage with mobility?	Immobile	0	
	Wheelchair independent including corners etc.	1	
	Walks with help of one person (verbal or physical)	2	
	Independent (but may use any aid e.g. stick)	3	
How do they manage with stairs?	Unable	0	
	Needs help (verbal, physical, carrying aid, stair lift)	1	
	Independent up and down	2	

The end, thank you!

Study ID ....

A. There are four sets of questions we would like you to answer over the next 19 pages. Please read the instructions for each set of questions.

Today's date:……………………………………………………..……………

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1. What is your name?……………..………………………………………………

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2. What is your relationship to the person in this study?

Please tick one box

Husband/wife/partner.……………..………………..….… ☐
Brother/sister.…………………………………………… ☐
Son/daughter…...……………………………………… ☐
Another relative (please specify in the box below)……... ☐

┌─────────────────────────────┐
│   │
└─────────────────────────────┘

A friend………………..………………………………… ☐
A paid carer………………..…………………………… ☐
Any other (please specify in the box below)…………...... ☐

┌─────────────────────────────┐
│   │
└─────────────────────────────┘

3. Are you

Please tick one box

in regular paid employment?.....................	☐
unemployed?...	☐
a student?..	☐
retired?…………..…………………………………..	☐
Full time carer of children?..........................	☐
Full time carer of an adult?...........................	☐
homemaker?	☐
semi-retired...	☐

4. Do you consider yourself to be a carer of the person in this study?

Yes	☐
No....................	☐
Lives in care home	☐

5. Over the past 4 weeks, how many hours per week, on average, did you give care to the person in this study?

	Hours per Week
Physical (washing, dressing, feeding)	
Domestic (Cleaning, laundry, shopping)	
Company (visiting, telephoning)	
Dealing with finances	
Household Maintenance (repairs, gardening)	

6a	Do you normally live with the participant	No	☐
		Yes	☐
6b	***If Yes:*** On a typical day, how much of the time can you leave the participant at home alone?	Not at all	☐
		Less than 1 hour	☐
		1-3 hours	☐
		3-6 hours	☐

	6-12 hours	☐
	Overnight	☐

7. Does the person you care for have any unpaid carers (apart from yourself)?

Please tick one box

Yes………………..… ☐

No………..…….…….. ☐

B. I am going to ask about different types of behaviour. We would like to know if any of these apply to the person you care for OVER THE LAST FEW WEEKS. Please answer ALL the questions by putting a tick in the box which you think most clearly applies to them. If things have changed over that time, respond for the last week.

1. Delusions: does the person have beliefs that you know are not true?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (beliefs present but seem harmless and produce little distress) ☐ **Moderate** (beliefs are distressing and disruptive) ☐ **Marked** (beliefs are very disruptive & are a major source of disturbed behaviour) ☐

2. Hallucinations: does the person have hallucinations, such as false visions or voices?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (hallucinations present but seem harmless and produce little distress) ☐ **Moderate** (hallucinations are distressing and disruptive) ☐ **Marked** (hallucinations are very disruptive & are a major source of disturbed behaviour) ☐

3. Agitation and Aggression: does the person have periods when he/she is agitated or aggressive? Or refuses to co-operate? Or won't let people help him/her with washing or dressing? Or shout or swear?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (behaviour is disruptive but can be managed with distraction or reassurance) ☐ **Moderate** (behaviour is disruptive and difficult to distract or control) ☐ **Marked** (agitation is very disruptive and a major source of difficulty; there may be a threat of personal harm) ☐

4. Depression: does the person seem sad or depressed? Does he or she say that he or she feels sad or depressed? Or a burden, a failure or a bad person? Or say he/she wishes to die or harm him/herself?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (depression is distressing but usually responds to distraction or reassurance) ☐ **Moderate** (depression is distressing, depressive thoughts are spontaneously spoken by the subject and difficult to alleviate) ☐ **Marked** (depression is very distressing, & a major source of suffering for the subject) ☐

5. Anxiety: Is the person nervous, anxious, worried or frightened? Is he/she shaky, tense or fidgety? Is he/she afraid to be in particular places or apart from familiar people?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (anxiety is distressing but usually responds to distraction or reassurance) ☐ **Moderate** (anxiety is distressing, anxiety symptoms are spontaneously voiced by the subject and difficult to alleviate) ☐ **Marked** (anxiety is very distressing & a major source of suffering for the subject) ☐

6. Elation: does the person seem abnormally cheerful or happy for no reason? Does he/she find things funny that others don't? Or tell silly jokes, or play tricks or pranks? Or boast about abilities or wealth?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (elation is noticeable by friends and family but is not disruptive) ☐ **Moderate** (elation is noticeably abnormal) ☐ **Marked** (elation is very pronounced; subject is euphoric and finds everything to be funny) ☐

7. Apathy and indifference: has the person lost interest in the world around him/her? Does he or she seem less interested in his/her usual activities and in other people? Or become less likely to start a conversation? Or seems not to have any motivation or not to care about things any more?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (apathy is noticeable but produces little interference with daily life; only slightly different from usual behaviour; subject responds to suggestions to do things) ☐ **Moderate** (apathy is very evident; may be overcome with coaxing and encouragement; responds spontaneously only to powerful events such as family visits) ☐ **Marked** (apathy is very evident and usually fails to respond to any encouragement or external events) ☐

8. Disinhibition: does the person seem to act impulsively without thinking about the consequences? Does he/she talk to strangers as if he or she knows them? Or say or do things that are rude or embarrassing? Or hurt people's feelings?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (behaviour is noticeable but usually responds to distraction or reassurance) ☐ **Moderate** (behaviour is very evident and difficult to overcome by carer) ☐ **Marked** (behaviour usually fails to respond to any intervention by carer and is a source of embarrassment or social distress) ☐

9. Irritability and temper: does the person get irritated easily? Or impatient? Do his/her moods change quickly? Does he/she get bad tempered? Or angry or argumentative?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur?	**Occasionally** (less than once a week) ☐ Often (about once a week) ☐ **Frequen**t (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (irritability or moodiness is noticeable but usually responds to distraction or reassurance) ☐ **Moderate** (irritability or moodiness is very evident and difficult to overcome by carer) ☐ **Marked** (irritability or moodiness is very evident, usually fails to respond to any intervention by carer and they are a major source of distress) ☐

10. Motor behaviour: does the person pace around or wander? Or engage in repetitive activities, such as opening cupboards or drawers, or picking at things, or winding threads?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur	**Occasionally** (less than once a week) ☐ Often (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (behaviour is noticeable but produces little interference with daily life) ☐ **Moderate** (behaviour is very evident but can be overcome by carer) ☐ **Marked** (behaviour is very evident and usually fails to respond to any intervention by carer & is a major source of distress) ☐

11. Sleep: Does the person have difficulty sleeping? Is he or she up at night (not including getting up once or twice to the toilet)? Does he/she get up at night thinking it is day? Is he /she sleepy during the day?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (every night) ☐
And how severe are the problems?	**Mild** (night time behaviours occur but are not particularly disruptive) ☐ **Moderate** (night time behaviours occur and disturb the subject and the sleep of the carer; more than one type of night time behaviour may be present) ☐ **Marked** (night time behaviour occurs; several types of night time behaviour may be present; the subject is very distressed during the night and the sleep of the carer very disturbed) ☐

12. Appetite: Has the person's appetite or eating habits changed? Has he/she lost or gained weight, or changed the foods he/she likes?	**Yes** ☐ **No** ☐
If yes, how often do these problems occur	**Occasionally** (less than once a week) ☐ **Often** (about once a week) ☐ **Frequent** (several times a week but less than every day) ☐ **Very frequent** (once a day or more) ☐
And how severe are the problems?	**Mild** (change in appetite or eating habits is present but has not led to change in weight & is not disturbing) ☐ **Moderate** (change in appetite or eating habits *is* present & cause minor change in weight) ☐ **Marked** (obvious changes in appetite or eating habits are present and cause weight change; is embarrassing or otherwise disturbs the subject) ☐

THE NEXT FEW PAGES OF QUESTIONS ARE ABOUT YOU THE CARER OR FAMILY MEMBER.

C. There is a list below of things which other people have found to be difficult when helping someone who has an illness. We would like to know if any of these apply to you OVER THE LAST FEW WEEKS. Please answer ALL the questions by putting a tick in the box which you think most clearly applies to you.

1. Sleep is disturbed (for example: because the person you care for is in and out of bed or wanders around at night)

Please tick one box

Yes………………...… ☐
No………....……….. ☐

2. It is inconvenient (for example: because helping takes so much time or it's a long drive over to help)

Please tick one box

Yes………………...… ☐
No………....……….. ☐

3. It is a physical strain (for example: because of lifting in and out of a chair; effort or concentration is required)

Please tick one box

Yes………………...… ☐
No………....……….. ☐

4. It is confining (for example: helping restricts free time or cannot go visiting)

Please tick one box

Yes………………...… ☐
No………....……….. ☐

5. There have been family adjustments (for example: because helping has disrupted my routine; there has been no privacy)

Please tick one box

Yes………………...… ☐
No………....…….….. ☐

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6. There have been changes in personal plans (for example: I had to turn down a job; could not go on vacation/holiday)

Please tick one box

Yes………………...… ☐
No………....…….….. ☐

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7. There have been other demands on my time (for example: from other family members)

Please tick one box

Yes………………...… ☐
No………....…….….. ☐

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8. There have been emotional adjustments (for example: because of severe arguments)

Please tick one box

Yes………………...… ☐
No………....…….….. ☐

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9. Some behaviour is upsetting (for example: because of incontinence; the person you care for has trouble remembering things; or the person you care for accuses people of taking things)

Please tick one box

Yes………………...… ☐
No………....…….….. ☐

10. It is upsetting to find the person you care for has changed so much from his/her former self (for example: he/she is a different person than he/she used to be)

Please tick one box

Yes…………….…..… ☐
No………....……….. ☐

11. There have been work adjustments (for example: because of having to take time off)

Please tick one box

Yes…………….…..… ☐
No………....……….. ☐

12. It is a financial strain

Please tick one box

Yes…………….…..… ☐
No………....……….. ☐

13. Feeling completely overwhelmed (for example: because of worry about the person you care for; concerns about how you will manage)

Please tick one box

Yes…………….…..… ☐
No………....……….. ☐

D. We should like to know if you have had any medical complaints and how your health has been in general, OVER THE LAST FEW WEEKS. Please answer ALL the questions by putting a tick in the box which you think most clearly applies to you. Remember that we want to know about present and recent complaints, not those you had in the past.

Have you recently…….

1. Been able to concentrate on whatever you're doing?

Please tick one box

Better than usual…………..………… ☐
Same as usual…………..…..………… ☐
Less than usual…………..…………….. ☐
Much less than usual……....……….. ☐

2. Lost much sleep over worry?

Please tick one box

Not at all……………..………………… ☐
No more than usual……..………….. ☐
Rather more than usual…..………… ☐
Much more than usual……..…..…… ☐

3. Felt that you were playing a useful part in things?

Please tick one box

More so than usual……..…………… ☐
Same as usual…………..…..………. ☐
Less useful than usual…...………. ☐
Much less useful…...…..…..………. ☐

4. Felt capable of making decisions about things?

Please tick one box

More so than usual……..………………   ☐
Same as usual…………...…………….   ☐
Less so than usual………..…………...   ☐
Much less than usual…………..………   ☐

---

5. Felt constantly under strain?

Please tick one box

Not at all……………………………………   ☐
No more than usual…………….…...….   ☐
Rather more than usual……………..   ☐
Much more than usual……………….   ☐

---

6. Felt that you couldn't overcome your difficulties?

Please tick one box

Not at all……………….…...…………   ☐
No more than usual……………..…...….   ☐
Rather more than usual…………..   ☐
Much more than usual……………….   ☐

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7. Been able to enjoy your normal day-to-day activities?

Please tick one box

More so than usual……..………………   ☐
Same as usual…………...…………….   ☐
Less so than usual……..…………...   ☐
Much less than usual…...…..….……   ☐

8. Been able to face up to your problems?

Please tick one box

More so than usual……………………… ☐
Same as usual……………..………… ☐
Less so than usual……..………..…….. ☐
Much less able…………………..………. ☐

9. Been feeling unhappy and depressed?

Please tick one box

Not at all…………………..………..…… ☐
No more than usual…………………… ☐
Rather more than usual…..………… ☐
Much more than usual……..………… ☐

10. Been losing confidence in yourself?

Please tick one box

Not at all………..…………………… ☐
No more than usual………..……….. ☐
Rather more than usual………….. ☐
Much more than usual……..…..… ☐

11. Been thinking of yourself as a worthless person?

Please tick one box

Not at all………………………………… ☐
No more than usual………..……… ☐
Rather more than usual…..…..… ☐
Much more than usual…..…..…… ☐

12. Been feeling reasonably happy all things considered?

Please tick one box

More so than usual……………………… ☐
About same as usual……..…..……… ☐
Less so than usual………...………….. ☐
Much less than usual……..…..……… ☐

Thank you for taking the time to complete the questionnaire