Dementia and Cognitive Impairment in the Older Prisoner Population of England and Wales: Identifying Individual Need and Developing a Skilled, Multi-Agency Workforce to Deliver Targeted and Responsive Services

Protocol

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Abbreviations

6-CIT	Six-item Cognitive Impairment Test
ACE-III	Addenbrooke's Cognitive Examination – Third Revision
BADLs	Bristol Activities of Daily Living Survey
BIA	Budget Impact Analysis
CIs	Confidence Intervals
CSO	Clinical Studies Officer
DH	Department of Health
GDS	Geriatric Depression Scale
HMIP	Her Majesty's Inspectorate of Prisons
ID	Identification
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
MCA	Mental Capacity Act
MoCA	Montreal Cognitive Assessment
MoJ	Ministry of Justice
NHS	National Health Service
NOMS	National Offender Management Service
OHRN	Offender Health Research Network
PI	Principal Investigator
RCT	Randomised Controlled Trial
RSN	Restore Support Network
SOPs	Standard Operating Procedures
SPOC	Single Point of Contact
SSC	Study Steering Committee
START	Short Term Assessment of Risk and Treatability

1. Project Summary

Background

Dementia is currently an NHS priority (Burns, 2014). In England and Wales, prisoners over 60 are proportionally the fastest-growing age group, followed by those aged 50-60 (Ministry of Justice (MoJ), 2015).With the continued aging of the prison population (Prison Reform Trust, 2011), dementia is likely to become a more and more significant issue and one that should not be ignored if the policy on equivalence for health services between prisons and the community is to be followed. The next obvious step is to develop dementia services in prison, including identification and care pathways. For this to happen, the prevalence of dementia in prison must first be established. Current estimates for dementia rates of 1-2% amongst older male prisoners (Fazel et al, 2001a,b; Kingston et al, 2011) are based on small, single-site samples, do not include women, and may thus not be representative of the general older prison population.

As the prevalence of dementia in prisons is established, gaps in current service provision can then be recognised and new care pathways designed. We expect that this will result in the identification of a number of training needs, not only in dementia care but also in how the Care Act (2014) will influence the provision of social care in prisons. It is hoped that following this project, further work on the prevention of dementia can be provided to prisons as is currently the case in the community (Barrett & Burns, 2014).

Research Question

What pathways of care, service provision and staff training packages should be provided to appropriately support older prisoners, aged 50+, with cognitive impairment, including dementia, in England and Wales?

Design

The research programme involves mixed methods and is divided into four key parts.

Part 1 - Prevalence study and validation of a short screening tool.

At least 860 male and female prisoners will be screened using the Six-item Cognitive Impairment Test (6CIT; Brooke & Bullock, 1999) and the Montreal Cognitive Assessment (MoCA; Nasreddine *et al.,* 2005). The MoCA will be used as a robust measure to estimate the prevalence of cognitive impairment.

Participants testing positive on the MoCA will be interviewed using the Addenbrookes' Cognitive Examination (ACE-III; Hsieh *et al.,*2013) and a range of standardised assessments to establish degree and type of impairment; risk of violence to self and others/victimisation; activities of daily living needs; mental health needs; history and symptoms of brain injury(if applicable); and social networks.

Data generated will then be used to estimate current and likely future prevalence of dementia or cognitive impairment in the prison population to inform the planning and costing of services.

Part 2 – Survey of current service provision

A questionnaire will be distributed to the healthcare managers and governing governors in all prisons in England and Wales holding adult men and women (n = 107). The questionnaire will ascertain current service provision for prisoners with cognitive impairment and identify the unmet training needs which would equip staff, including clinicians, prison officers and other professionals working in prison, to better meet the identified needs.

Part 3 – Focused Ethnography and semi-structured interviews
Approximately 10 individual prisoner case studies will be identified from part 1 data. A focused ethnography approach will be employed involving short-term observations of discrete events and semi-structured interviews will take place with those experiencing cognitive impairment and a range of people they interact with. This will identify the specific problems experienced by people with differing levels of severity of cognitive impairment, solutions currently used and improvements that should be made.

Part 4 – Care pathway and training package design and costing.
Data from Part 1 will be used to produce detailed case vignettes describing several archetypical cases of varying levels of severity of cognitive impairment and these will be presented to a panel of experts. The panel will then design pathways of care for cognitive impairment of varying severity and will contribute to the development of a training pack for the identification of cognitive impairment for staff working in prison. Our health economist will estimate and aggregate the costs of these packages of care in relation to Part 1 prevalence data.

Start date: 01/07/2016
Duration: 36 months

2. Research Aims and Study Objectives

We will validate a standard assessment tool and develop both care pathways and staff training specific to the prison environment, which will improve the quality, accessibility and organisation of services for older prisoners. We aim to increase staff confidence in identifying and supporting older prisoners with cognitive impairment/dementia and to move towards equivalence of prison-based care with community provision.

In England and Wales:

1) Estimate prevalence of cognitive impairment including dementia amongst the older prisoner population;

2) Validate the Six Item Cognitive Impairment Test (6CIT; Brooke & Bullock, 1999) for prisoners aged 50+;

3) Identify service needs and appropriate care pathways for older prisoners with cognitive impairment throughout custody and on discharge to the community;

4) Establish prison and healthcare staff training needs for identifying, assessing and supporting cognitively impaired older prisoners; and

5) Develop an appropriate training support pack.

3. Background

Across the developed world, the number of older adults in prison is rising (Moll, 2013). In England and Wales, prisoners aged over 60 years are proportionally the fastest-growing age group, followed by those aged 50-60 (Ministry of Justice (MoJ), 2015). Between 2004 and 2014, the number of older male prisoners has more than doubled from 1,655 to 3,720 aged over 60 years and 5,268 to 11,980 over 50 years. At the same time, the number of women over 60 has increased almost fourfold, from 25 to 96, while those over 50 have also more than doubled, from 209 to 437 (MoJ, 2015). A similar pattern has been shown in other countries, including the US (West, Sabol & Greenman 2010), Australia (Grant, 1999), Japan (Yamaguchi, 2011), and Canada (Uzoaba, 1998). This trend is likely to continue (Prison Reform Trust, 2011).

There are a number of reasons to account for this unprecedented rise. The most important of these is the increase in the ageing population as a whole (Howse, 2003). However, there have also been some changes within the criminal justice system which have had an impact on the increased older prisoner population (Hayes et. al., 2012; Moll, 2013; MoJ, 2010).

Despite these rises, older people can go unnoticed in large prisons. Unlike their younger counterparts they tend to be quieter and less complaining and their health and social care needs may not be as immediately obvious as those with severe, acute problems such as active psychosis or substance withdrawal. This was notably emphasised in the thematic review published by the Chief Inspector of Prisons (HMIP) in 2004, *No Problems – Old and Quiet,* the title reflecting an entry found in an elderly prisoner's discipline record. However, this stereotype of a quiet, helpful, older prisoner is being challenged by the growing body of research showing that they can have serious health, social and custodial needs which often go unidentified and unmet in the prison setting. A number of studies have shown that older men in prison have different needs to both the general (younger) prisoner population and also to older adults in the community (Crawley & Sparks, 2005; Fazel et al 2001a, b; Hayes et al 2012, 2013; Wahadin, 2004; Ware, 2009).

It is a firmly established policy principle that healthcare services for prisoners must be equivalent in quality and range as those provided in the community (Department of Health [DH], 1999). All National Health Service (NHS) standards therefore apply to prison healthcare, including the *National Service Framework for Older People* (DH, 2001). However, the standards outlined in this framework remain largely unmet in prisons in England and Wales (HMIP, 2008) and there remains no overarching national strategy for older prisoners despite repeated recommendations for one to be developed (HMIP, 2008).

While the general health and social care needs of older prisoners have often been unrecognised, this is particularly true for older prisoners with cognitive impairment or dementia. There have been very few studies examining this, and the most robust evidence comes from countries outside the UK (Barak et al, 1995; Fazel & Grann, 2002). Prevalence estimates also vary (Fazel et al, 2001; Hayes et al, 2012; Kingston et al, 2011), possibly due to discrepancies in the assessment measures used. However, whatever the true prevalence, the research shows that there are people with dementia in prison, and there are a number of ethical issues to be considered with this group. Fazel et al (2002) discussed conceptual reasons for incarcerating offenders, including; as a deterrent to others from committing crimes, removing criminals from society thereby preventing crime during that period, for rehabilitation, for retributive justice, or for the symbolic purpose of expressing 'disapproval' for crime. The authors suggested that some of these issues are problematic with regard to prisoners with dementia, and discussed in detail the ethical issues around imprisoning those who are neither aware of where they are nor why they are there and what illegal acts they previously committed. These ethical considerations are important but also the aging of the prison population may mean that there is a need for practical consideration of the management and housing of prisoners with dementia.

There is therefore a need for studies to examine the wide-ranging needs of those with dementia, including their daily living skills, on-going risk etc. to fully establish service requirements.

The next obvious step is to develop dementia services in prison, including identification and care pathways. For this to happen, the prevalence of dementia in prison must first be established. Current estimates for dementia rates of 1-2% amongst older male prisoners (Fazel et al, 2001a,b; Kingston et al, 2011) are based on small, isolated samples, do not include women, and may thus not be representative of the general older prison population. With regard to cognitive impairment, Hayes et. al. (2012) investigated a sample of older, male prisoners drawn from a one-day census in 12 prisons across North-West England. They reported that the Mini Mental State Examination scores 7% of participants indicated the need for a further assessment. An accurate prevalence rate will allow an understanding of the current ability of services to identify and manage prisoners with dementia or cognitive impairment and an awareness of their needs. Studies have shown that prisoners with dementia or cognitive impairment can suffer from multiple adverse consequences in relation to victimisation and punishment for non-adherence to prison rules (Dawes, 2009; Stojkovic, 2007). This condition should be detected early with suitable care provision. This study will therefore explore the validity of employing a short screening tool for cognitive impairment.

As the prevalence of dementia in prisons is established, gaps in current service provision can then be recognised and new care pathways designed. We expect that this will result in a number of training needs, not only in dementia care but also in how the Care Act (2014) will influence the provision of social care in prisons. It is hoped that following this project, further work on the prevention of dementia can be provided to prisons as is currently the case in the community (Barrett & Burns, 2014).

4. Study Part One

Part one of the study will seek to:

- Validate the 6CIT for routine use in prisons to aid early and consistent identification of older prisoners with possible cognitive impairment or dementia.
- Establish the degree and type of impairment; risk level, needs and social networks of those who screen positive on the MoCA.
- Estimate the current and likely future prevalence of dementia in the prison population in England and Wales

a. Stage One – Validation of the 6CIT

i. Sample

We will aim to recruit at least860 prisoners aged 50 and over, including 269 women and 591 men. Within each sex, this sample size will allow the estimation of a prevalence of 7% (based on Hayes et al., 2012) with 2% precision (95% confidence intervals (CIs) 5% to 9%, applying finite sample corrections for each sex).

Sampling Procedure

We have developed our sampling procedure based on a review of the existing literature.

The sample will be drawn randomly from all female prisons and a representative range of adult male prisons across England and Wales, including local prisons holding those on remand, serving short sentences and in the early part of long sentences; training and dispersal prisons holding men part-way

through long sentences; high secure establishments holding those considered to be high risk; and open prisons holding short term prisoners deemed low risk and those in the final stages of long sentences, who are preparing for community release.

We have selected sites based on the proportion of each prison type in the prison estate as a whole- 1 of the 8 high secure sites; 3 of the 31 locals; 5 of 51 category B or C training and dispersal prisons and 1 of the 7 category D/open prisons (as defined by the justice.gov.uk prison index – accessed 9th May 2016). We will also include a prison that has a specific wing for older and disabled prisoners. This is one of only two prisons in the country with a dedicated wing for prisoners based on their age and health needs. However, other prisons do have a large number of older prisoners as a result of them housing vulnerable prisoners (i.e. prisoners who are considered at risk from other prisoners, often due to their age or the nature of their offence).

We estimate that we will need to initially approach approximately 415 females and 896 males to allow for 20% refusing to participate and a further 14% who may be unavailable on the day; unable to consent; or have already been interviewed for the study in a previous establishment. (These estimates are based on Hayes et al. 2012 study, in which researchers conducted a one-day census of all prisons in North-West England and interviewed all males aged 60+ resident in each establishment).

We will establish the total number of prisoners aged 50+ in the recruiting prisons and use these figures to calculate a sampling fraction, which will inform the proportion of prisoners we will approach at each site. For example, if there are a total of 1500 males aged 50+ in the prisons we approach, we will sample 60% of older prisoners at each site(896/1500). We will also stratify our sample according to age, an important variable when investigating cognitive impairment, as prevalence doubles with every increase of five years (Jorm & Jolley, 1998). We will therefore aim for half of our overall sample (for males and females) to be aged 50-69 years and half to be aged 70+.

We will review the recruited sample at regular intervals, pausing recruitment briefly (initially after we have recruited one quarter of the sample) and reviewing the sampling strategy, to consider, for example, whether we need to recruit a greater proportion of a particular age group. The first phase of recruitment (after one quarter are recruited) will effectively act as a pilot for the remainder.

Inclusion/Exclusion criteria

Anticipated inclusion criteria:

i) Aged 50 or over;
ii) Resident in one of the participating prison establishments on the day of the census.

Anticipated exclusion criteria:

i) Considered by prison or healthcare staff not safe to interview alone due to their current risk assessment;
ii) Previous inclusion in the study;
iii) Does not have a functional command of the English language.
iv) Lacking the capacity to provide informed consent AND an appropriate Personal or Independent Consultee cannot be identified/contacted, is unwilling to be consulted or makes the decision to refuse consent.

Participants will only be included if they can speak and understand English to a sufficient level and researchers are satisfied that their English language ability will not adversely impact their test scores. There are significant language biases in some tests, which cannot be overcome by straightforward translation or use of an interpreter. Some tests are available in other language

versions but not all translations have been validated and test administration would still require the presence of an interpreter. In previous, prison-based studies, researchers have experienced considerable difficulties in accessing Language Line or similar resources. The equipment required to utilise these resources is scarce within prisons and negotiating researcher access to it on an ad hoc basis is not realistic and would threaten the feasibility of completing the research to time and budget.

ii. Procedure

Our exact procedure may vary between sites, as certain elements will depend upon local factors or procedures, such as the size of the healthcare suite/holding room; the freedom of movement allowed to prisoners within the establishment and whether or not researchers are authorised as key holders. The research team will therefore liaise with the prison governor and relevant staff to establish a procedure in each site, which broadly follows that detailed below.

Recruitment

We will utilise a one-day census approach, specifying a census date per site. (It is not feasible to have only one census day for all sites, as it will take considerable time to collect data at each site and a long delay between the census date and data collection would inevitably result in increased attrition, especially at local prisons with transient, remand populations).As stated previously, we will pause recruitment when we have recruited one quarter of the sample and will conduct descriptive analyses on existing data to determine whether any changes need to be made to our recruitment strategy. For example, whether we need to focus on recruiting more of the oldest old aged 70 or 80+.

A research nurse or other appropriate staff member within each of the prisons will act as a single point of contact (SPOC) for the research team. (This may be a different role across study sites (such as a Clinical Studies Officer (CSO), researcher or research facilitator, but we will ensure the individual is not in a directly caring role for prisoners, to avoid the potential for coercion during recruitment). The research team will provide the SPOC at each site with a census date and the SPOC will then identify potential participants who fulfil the inclusion criteria. They will do this by running a search on all prisoners in their establishment on the prison computer system (C-NOMIS) or healthcare system (Systmone). Once a numbered list of all potential participants has been generated, the SPOC will inform researchers of the number of eligible older prisoners they have identified. A member of the university-based research team will then use a random number generator to identify the numbers of those randomly selected for potential participation and will communicate these to the SPOC e.g. numbers 1, 3, 6, 7, 9....on this list. The SPOC will then conduct checks using the internal prison data systems to ensure that the individual meets the inclusion criteria and it is appropriate for them to be seen by the research team. For example, are they currently mentally and physically well enough to be seen; are they considered safe to be seen? It is inappropriate to use Criminal Justice staff, including prison health care staff, to make the first approach because of the potentially coercive (or perceived coercive) nature of the relationship in the prison environment

The SPOC will then send an information and appointment slip to each of the individuals who have been randomly selected and are both eligible and appropriate to be seen. The slip will very briefly outline the study and will invite each individual to a one-to-one interview with a researcher. The slip will explicitly state that by attending their designated appointment, individuals will be meeting with a member of the research team to further discuss the potential for participation. Details of who to approach for further information or advice regarding the study, within the prison and prior to the appointment time, will also be included. (Interviews may be held in healthcare clinic rooms, in visits or in wing interview rooms, depending on the availability of rooms, procedures and governor preferences within each prison). This procedure is being followed in a current study which the PI is

involved with and is more realistic and feasible than having someone within the prison going to see each potential participant and asking for their consent to pass details on to the research team. There may be in excess of 100 potential participants at some establishments and given the impact of austerity measures across the prison estate, requiring a member of staff to do this amount of work on our behalf would be a major barrier to completing the project. It would also be unfair to potential participants if this process was rushed or not done properly.

At their appointment time, potential participants who choose to attend will meet a researcher, who will provide them with initially verbal and then, if willing, written information about the study and an opportunity for further discussion. During the briefing process, participants will be made aware that if they choose to take part in the study, their data will be made available to other researchers, but that this will be in an anonymised format.

Following the procedure for obtaining consent as outlined below, if an individual consents to taking part, the researcher will conduct an initial interview, which will include the collection of demographic data and completion of the 6CIT and MoCA.

Researchers will obtain the prison ID number of all who attend an appointment, regardless of whether they agree to participate in the study. This list will then be passed to the SPOC, who will match it against the list of those invited to appointments to identify anyone who failed to attend. If any individuals identified in the initial random sample fail to attend, the SPOC will attempt to make contact with them and ensure that the reason for their failure to attend was not related to an inability to comprehend the written information provided or to attend the appointment. This is an important step in ensuring that the sample is not biased by the indirect exclusion of those with a cognitive impairment. The SPOC will take great care to avoid coercing individuals into taking part or making individuals feel they have to account for their decision not to attend. Instead they will make it clear that the purpose is to check whether any individuals wanted to attend but were unable to, in which case, appropriate arrangements and additional support will be put in place to facilitate a meeting with the research team.

If the initial, randomly-selected sample from each site falls short of our recruitment target, researchers will randomly generate further numbers for the SPOC to check against eligibility criteria and invite to a meeting with researchers, until the target is reached.

Consent

The researcher will explain the project to the potential participant and will give them the information sheet as well as explaining their ethical rights (included in the appendices). The researcher will read and explain the information in these documents to the potential participant, showing sensitivity to the high levels of learning difficulties in this population and potential cognitive impairment.

At the beginning of the appointment the researcher will go through the information sheet and answer any questions that the prisoner wishes to ask. The researcher will explain what participation involves and how much time participation will take. They will also explain that participation is voluntary, that the prisoner is free to withdraw at any point and that their decision to participate, or not, will have no adverse effect on the care they receive or their other legal rights. The researcher will also discuss the arrangements to ensure confidentiality (and limits of this) and data protection. Limits to confidentiality would include information pertaining to:

- Behaviour that is against prison rules;
- Information that either suggests a risk of harm to self or others;

- Information that refers to a new crime committed or planned or undisclosed illegal acts;
- Behaviour that is harmful to the individual (e.g. intention to self-harm or end one's life) and;
- Information that raises concerns about terrorism, radicalisation or security issues.

Researchers have a duty to inform prison staff of any such information.

Potential participants will be given the option of participating immediately after being approached. The reason for interviewing people so shortly after the initial approach is because of the complex and challenging nature of the prison environment; the difficulties in working around the prisons' security needs (which take priority at all times) and the very short notice periods over which people can be moved around the prison estate. Potential participants who wish to have longer to consider their involvement will be interviewed within a week of initial approach and will be given at least 24 hours to consider whether to participate. The consent form will be explained to the participant before they sign it and the researcher will sign the form after it has been completed by the prisoner. A copy of the consent form will be offered to the prisoner and one copy retained by the researcher. Once informed consent has been obtained, the prisoner will be invited to begin the interview.

Each person who agrees to participate in the interview will be allocated a unique 'Participant ID number', so there will be no need to record the prisoner's name on the survey questionnaire. Depending on the outcome of the initial screening, participants maybe invited for a further interview. Participants will be given the option of whether they wish to be contacted in the future (within three months) to take part in a further interview should they be eligible. For those who do not want to continue with the study, they will be thanked for their time and the study will end. For those who do show interest in the possibility of a further interview, it will be explained that they may be contacted in the next three months. It will be made clear that the participant is under no obligation to complete the next interview should they change their mind.

The researcher taking consent will be aware of the potential for any coercion and how the vulnerabilities of individuals might affect the decision they make. Researchers will also receive specific training in recognising cognitive impairment and working sensitively with individuals affected in this way. The researchers will be aware of the potential, and trained to look for, undue influences on potential participants. Researchers will emphasise that participants can withdraw at any time without having to give a reason, and that this will not yield any consequences. The prisoner population has high levels of illiteracy and learning difficulties and researchers will also have an awareness of these difficulties when obtaining consent. Information pertaining to learning existing learning difficulties will be collected during interviews and when reviewing healthcare records given the potential of such difficulties to influence cognitive test scores. Researchers will ensure that participants can demonstrate a clear understanding of their involvement in the study and their rights within the study (e.g. the right to withdraw) prior to seeking informed consent. Researchers will be sufficiently trained/experienced to assess whether patients have the capacity to give consent.

Individuals Lacking Capacity

Researchers will receive training in assessing capacity using the two-stage process outlined in the Mental Capacity Act (MCA; 2005).

Where necessary, because of someone's level of cognitive impairment, we will seek informed consent from participants using the widely Dewing's (2007) widely accepted process consent method. This method seeks to include people with dementia in research by reaffirming consent at each contact, rather than as a one-off process. The steps involved in the process consent method

are: 1. Gaining "permission to access" the person with dementia from staff, a relative or named person (see below). This also involves finding out some biographical information about the person with dementia 2. Establishing the basis for consent - as capacity is situational and variable, the researcher endeavours to find out how the person usually consents to care or other activities in day-to-day life 3. Initial consent for the specific research is sought. Information is provided that is appropriate for that person to help them understand the study. This step includes recording nonverbal communication and facial expressions and referring back to what is already known about how the person usually consents on a daily basis. It is important that the researcher does not rely only on a lack of verbal objection and assumes this to mean consent has been given 4.Ongoing consent monitoring highlights the idea of consent as a process. Dewing (2007) described this stage as "*ensuring initial consent is revisited and re-established on every occasion or even within the same occasion*" 5. Feedback and support. This includes feeding back to staff any concerns the researcher may have about the participant.

The consent process above will be completed in line with the MCA (2005) and good clinical practice principles. Researchers will seek an opinion from prison healthcare staff regarding capacity and will attempt to identify a "Personal Consultee" as defined by the MCA (2005) to advise on the individual's participation. In the first instance, even where participants are considered to lack the capacity to consent to participation, researchers will ask if they may contact someone else to advise on the individual's behalf and will ask the potential participant's permission to contact a nominated individual. Potential consultees from outside of the prison will only be contacted if the research team can establish that they are aware that the potential participant is in prison and that they have difficulties which limit their capacity to consent. The initial approach to anyone outside of the prison will be made by prison healthcare staff. Personal Consultees will be provided with study information and their role and the reason for them being approached will be explained by researchers. If the participant is unable to nominate anyone or give consent to contact someone outside of the prison, researchers will identify an appropriate independent consultee (again in line with the MCA, 2005). This will most likely be a clinician or healthcare worker from within the prison. No pressure will be placed on any individual to act as a consultee and researchers will fully brief consultees regarding the study, to enable them to offer advice on the potential participant's behalf. If a consultee or nominee advises that the individual would not want to take part, they will not be recruited under any circumstances.

Researchers will also discuss the study with the person themselves in a way appropriate to their level of understanding. If there is any indication that the individual does not agree with any part of the study, the individual will not take part even if their participation has been advised by another person on their behalf. If this occurs, researchers will inform the individual's consultee that the individual will not be taking part, despite their advice and will explain the reasons for this. There is clear potential for the research to benefit individuals with cognitive impairment and the study methods (interviews and observations) pose minimal risk to participants. All data collection will be completed with sensitivity and respect for the autonomy and privacy of each participant.

The following safeguards will apply once an individual has been recruited in this way:

- No actions will be taken during any part of the study if the participant seems to object to it (unless the action is vital to protect the individual from harm).
- Researchers will consider the interests of the participant above all else throughout the study.
- The participant will be withdrawn if any conditions pertaining to his or her inclusion in the project no longer apply and/or if he or she gives any indication of not wanting to continue or take part.

The consent form for all individuals will include an option to indicate a preference for or against continued participation, should the individual lose the capacity to consent during the study.

Measures

6-CIT (Brooke & Bullock, 1999)
The 6CIT is a short screening measure for dementia. It is administered in around 3-4 minutes and asks questions about the current time, month and year, as well as testing the participant's ability to recall a five-component address and list the numbers 1-20 and the months of the year in reverse. Permission to use the measure has been obtained from the authors.

MoCA (Nasreddine et al., 2005)
The MoCA was designed as a rapid screening instrument for mild cognitive dysfunction. Different cognitive domains (including attention, memory, visuo-spatial skills and orientation) are assessed using a series of short tests. The time taken to administer the MoCA is approximately 10 minutes. The total possible score is 30 points with a score of 26 or above considered normal. Permission is required to use the MoCA for research purposes and it has already been granted in regard to this study.

iii. Data Analysis

The principal approach will be to examine the capacity of the 6CIT to detect cognitive impairment including dementia at different recognised levels. The approach employed in these analyses would be the measurement of agreement between categories using Kappa (e.g. Cohen, 1960; Fleiss, 1975; Kraemer, 1992). We will also examine the relationship between the items and combinations of items on the scales, and with this ordered data, will employ weighted kappa as the measure of agreement (Cohen, 1968; Dunn, 1989). This will establish whether the 6CIT has suitable psychometric properties to be used as a routine screen in prisons. We will estimate the prevalence of cognitive impairment by calculating percentages and 95% confidence intervals (CIs) using the 6CIT, for comparison with prevalence estimates based on the MOCA. We will estimate the sensitivity, specificity, false positive rate and false negative rate for 6CIT, using the MOCA as a robust, validated measure. From the MoCA and ACE-III score stratification into mild, moderate and severe, we will select individuals for further interview in Part 3 and create the vignettes in Part 4.

b. Stage Two - Full needs assessment

i. Sample

Those who screen positive on the MoCA in stage one and consent to a further interview, will be invited to meet again with researchers.

ii. Procedure

The full needs assessment interview may take place immediately after the part one interview or may be delayed by a short time, depending on the operational arrangements at each study site and the individual's preference or needs. A further, fairly lengthy interview may be difficult and distressing for individuals with cognitive impairment, so researchers will consider the needs and wishes of each participant prior to continuing with stage two. If it is operationally a viable option and the individual is able and willing to continue with a full needs assessment, then both interviews may be conducted at the same appointment. If this is not the case, the researcher will arrange a new appointment via the research nurse and will return to complete the full needs assessment at a different time. As far as possible, the time between interviews will be kept at a minimum, to maximise the validity of results

(as individuals with cognitive impairments may fluctuate in their cognitive ability and lucidity from day to day and/or their abilities may deteriorate over even short periods of time).

Interviews and consent procedures will follow the same format as described above (stage one). Researchers will first obtain additional, more detailed demographic information, as these data will be required to accurately describe the population with an indication of cognitive impairment or dementia in prison. Further questions will also be asked which pertain to the individual's current physical and mental health as well as any diagnosis of learning difficulties or disabilities, sensory difficulties and/or use of substances/medication. This information is required in order to gauge the presence of other factors known to impact on cognitive test scores, (e.g. pain, strong medication, poor hearing/eyesight, learning issues, mood disorders). Researchers will also then interview participants using a range of standardised assessments to assess their degree and type of impairment:; activities of daily living needs; mental health needs; brain injury; and social networks. Subject to each individual's informed consent, risk and follow-up data will also be collected at this stage. Information pertaining to risk of harm and re-offending will be sought from the Offender Management Unit. The NHS number, name and date of birth of each participant will also be obtained and recorded to allow for the long-term follow-up of key health and criminal justice outcomes at a later date. At this stage, consent will also be sought from the participant (or advice from the consultee) with regard to researchers accessing the individual's electronic, prison healthcare record. Healthcare records will be screened for any indication of cognitive impairment or dementia and for any of the other test-influencing factors mentioned above.

Measures

Addenbrookes Cognitive Examination – Third Revision (ACE-III: Hsieh et al., 2013). The ACE-III is one of the most commonly-used cognitive tests used to assess dementia and other neurological disorders. It routinely takes around 15 minutes to administer and covers five domains: attention; memory; fluency; language; and visuo-spatial ability.

Bristol Activities of Daily Living Survey (adapted version: Bucks et al., 1996). The BADLS, adapted version was designed specifically for patients with dementia. The questions assess level of independence with regard to daily living abilities, such as preparing food, dressing, washing and using the telephone. The BADL's 20 items will be reduced to 18 for the purposes of this study, as questions relating to activities which are not relevant in prison (use of public transport; managing finances) will be removed. Questions about shopping and housework will be re-phrased to relate to canteen ordering and keeping one's cell area clean. It can be administered in approximately 5 minutes.

Geriatric Depression Scale (Sheikh & Yesavage, 1986). The GDS-15 is an adapted version of the GDS Long Form and is used to identify depression in the elderly and takes around 5 minutes to complete.

PrisnQuest (Shaw, Tomenson & Creed, 2003). PrisnQuest is an eight-item prison screening questionnaire validated to screen for mental illness in prison. The questions are in yes/no format and cover previous contact with services, suicidal ideation and the presence of psychotic symptoms. A score of three or more indicates the need for further, detailed examination and the measure can be completed in less than five minutes.

Rivermead Post-Concussion Symptoms Questionnaire (King et al., 1995).The RPQ was designed to assess the presence of mild to moderate brain injury. Participants are asked to rate the severity of 16 cognitive, somatic and emotional symptoms, commonly found after a traumatic brain injury. Symptoms are rated from "0: not-experienced" to "4: severe problem" and are judged for their severity over the course of the last 24 hours. The questionnaire takes around 5 minutes to administer

and will only be administered to participants who report having had a brain injury, as it is not relevant to non-brain-injured individuals.

Lubben Scale (modified version: Lubben, 1988). The LSNS-18 is an eighteen-item self-report scale to assess social isolation in older adults. It measures perceived social support from family, friends and neighbours. The LSNS takes around 10 minutes to complete and assesses the size, closeness, and frequency of contacts in a participant's social network. For the purposes of this study, "neighbours" will be interpreted as friends/acquaintances within the prison (rather than the individual's neighbourhood), while the section on friends will be completed in relation to friends external to the prison establishment.

Risk Information

Subject to each individual's informed consent, we will seek the following information from the Offender Management Unit within each prison, (with regard to each individual who participates in stage two):

- **OASys risk of harm rating:** Very high, high, medium, low
- **Risk Matrix 2000 score (in relation to risk of sexual re-offending)** if applicable**.**
- **Risk Markers** – sexual offender/risk to children/females/staff/hate crime e.g. racism**.**

Risk information will be used to describe the sample in stage two and to relate to what happens to prisoners with cognitive impairment (CI) or dementia in custody and on release. It will also be an important consideration during the care-planning workshops (part four) as risk management is a key element of deciding upon appropriate care pathways and alternative accommodation or services for prisoners with CI or dementia.

Procedure and Data Management

If a prisoner participant gives their consent for the research team to access risk information, data will be sought via an OMU administrator, who can generate a report based on the individual's prison ID number. A spreadsheet, containing only prison ID numbers; (which are not identifiable without access to the identifier key – the prison electronic information system CNOMIS); and fields for completion of the risk information as above (Oasys risk of harm rating; RM200 score, if applicable; and risk markers) will be shared via secure email – (nhs.net and gsi.gov.uk) domains between OMU administration and the research team. It would be most appropriate to complete this process on a prison-by-prison basis, in order that the individuals accessing records on behalf of the research team are those who are already doing so as part of their core role.

Once received by the research team, risk data will be fully anonymised, as it is entered into the main study database, using only the study participant identifier, (generated upon recruitment for each participant). As per our protocol version 1, the personal identifier (a three-digit number), will be used to link the identifiable and non-identifiable data. The identifier key will be stored securely and separately from outcome data. Furthermore, risk data will only be published as a description of the entire sample, so no individual will be identifiable.

Follow-Up

In order to follow-up on the longer-term health and criminal justice outcomes of those who screen in and participate in stage two (at a later date and with further funding) we will seek permission from participants to collect their NHS number as well as their full name and date of birth. We will explicitly ask participants if they are happy for us to follow-up on these outcomes at a later stage.

If consent is granted, researchers will obtain this information from a healthcare administrator who already has access to this information and data will be shared via secure email – (gov.gsi.uk and nhs.net). Participants will have been allocated a unique study identifier during part one, stage one, so once NHS numbers are received by the research team, they will be held with other identifiable information (name, prison ID number) in a separate and secure location to the identifier key and other study data including test responses.

Consent

Participants will be able to opt out of allowing access to their data for follow-up, and/or allowing access to their risk data as generated by the OMU, to maintain individual choice and avoid any potential adverse effect on recruitment. Prisoner participants will therefore be given the option to continue to participate in the study as a whole, even if they opt out of allowing researchers to access their risk information or follow-up data.

Individuals Lacking Capacity

No risk or follow-up information will be sought in relation to participants deemed to lack the capacity to provide informed consent, as it will not be appropriate for a personal or independent consultee to grant researchers access to risk or follow-up data on another's behalf.

iii. Data Analysis

This battery of tests will establish the broader needs of each older prisoner, including social support, daily living skills, co-morbidity and risk. Descriptive statistics will be produced. This information will inform the case vignettes in part 4; the analytical approach that we will use is outlined in detail in part 4 (please see 'stage 1: User profiling').

c. Stage Three – Prevalence study

Estimates will be calculated for current and for projecting future prevalence. We will generate a matrix of future prevalence estimates according to various hypothetical projected scenarios of overall prison population growth and of rising numbers of older prisoners in both absolute and proportional terms. If we have sufficient power in our final sample, we will produce age-standardised prevalence ratios and age-specific prevalence estimates, to allow comparison with community-based samples (e.g. Matthews et al, 2013). These estimates will be of intrinsic interest and value, and we will also use them to inform part 4, stage 4.

5. Study Part Two

Part two of the study will utilise a questionnaire to ascertain what health and social care services currently exist to identify and provide care for older prisoners with cognitive impairment and dementia in prisons, including how well multi-agency services are integrated. In addition, the questionnaire will explore levels of staff competency and confidence in this area, including identifying gaps in training and a detailed section on how any required training may best be delivered.

i. Sample

In part two of the study, a questionnaire will be issued to the governors and healthcare managers of all prisons housing adults, men and women, in England and Wales (n = 109). An up-to-date list of names and contact details of all health care managers will be obtained from the Offender Health Division at NHS England and cross-checked against records held by regional offender health leads. The questionnaire will be piloted in prisons in the North West of England before wider distribution. If any changes are made following the pilot, new or different questions only will be sent to the pilot prisons.

ii. Procedure

Our questionnaire will ascertain what health and social care services currently exist to identify and provide care for older prisoners with cognitive impairment and dementia, including how well multi-agency services are integrated. In addition, the questionnaire will establish the numbers and age distribution of prisoners aged 50 or over resident in each establishment; and will explore levels of staff competencies and confidence in this area, including identifying gaps in training and a detailed section on how any required training may best be delivered.

The questionnaire will be distributed electronically and sites followed up by email 2 weeks after the initial distribution of questionnaires; by telephone after a further 2 weeks; and by letter after an additional 2 weeks for those still outstanding. Governors/managers will be given the option of completing the questionnaire by telephone interview with a member of research staff. This method has previously resulted in an 80% response rate (Senior *et al*., 2013).

iii. Data analysis

Descriptive statistics, including percentages (95% CI), mean (standard deviation) and median (interquartile range) values, will be generated for the whole older prisoner population and with the analyses stratified by prison type and by geographical area. These data will illustrate service provision, workforce competencies and training needs. These descriptive profiles will inform part 4.

6. Study Part Three

To explore the experiences of older prisoners with cognitive impairment and dementia we will conduct a focused ethnographic qualitative study of a small number of individuals (Gustafsson et al, 2013). Semi-structured interviews will also be held with a range of individuals identified in part 1 as meeting the MoCA cut off score to indicate impairment and a number of prisoners identified via the part 2 questionnaire as having a diagnosis of cognitive impairment or dementia. Relevant individuals supporting these prisoners and those in key strategic positions will also be invited to participate in semi-structured interviews.

Focused, time limited, ethnography is a valuable research method for capturing experiences of dementia (Hubbard, Downs & Tester, 2003; Holthe, Thorson & Josephson, 2007). The observation will identify important aspects of care, or barriers to support, that may not be picked up in the semi-structured interviews and provide rich data around the discrete contextual and environmental influences of being in prison with dementia and how that differs from the community. Hubbard *et al*. (2003) suggest that the proposed combination of observation and flexible qualitative interviewing is an effective way of privileging the voice of people with dementia in order to understand the quality of life in care and institutional settings, thus is highly relevant to the proposed work. These combined methods are likely to reveal important issues with implications for training about the level of communication and interaction, as demonstrated in other institutional ethnographic studies

(Sarangi& Roberts, 1999). Observations of the prison environment and regime as experienced by participants with suspected cognitive impairment and dementia will have implications for planning and managing institutional opportunities for supporting prisoners with cognitive impairment and dementia. Again, the latter will provide important data to feed into the design of training in the subsequent phase.

a. Stage One: Focused Ethnography

i. Sample

A purposive sample will be recruited. We will aim to identify approximately 10 individual prisoners from part 1 of the study, including both male and females and those with a range of severity of cognitive impairment from different types of prisons. Additionally, a question will be included in the part 2 survey which will ask healthcare managers to specify if they are aware of any prisoners currently held in their establishment that are currently experiencing cognitive impairment/dementia. If we are not able to recruit a sufficient range of individuals from part 1 of the study we will ask the healthcare managers to ask these individuals for permission to pass on their details to the research team. The same informed consent process, as detailed in part one above, will be followed.

ii. Procedure

The approach to conducting the focused observations will be pragmatic and flexible, with observations concentrating particular attention on aspects of prison life where there is contact and interaction with other prisoners and staff which will vary, according to different institutional contexts. Focused ethnographic observations of each person undertaking discrete, time-limited tasks and activities will be undertaken and detailed field notes will be made.

We know from our experience of research in prisons that the prison routine for individuals consists of key events for most prisoners on most days. These include multiple communal activities including meal times, exercise, and focused work or educational activities and interaction with health care providers, where appropriate. Specific examples of activities we would wish to observe would include:

- Collecting meals from the wing servery;
- Cell cleaning;
- Clothes washing and kit changing;
- Shopping for personal items via prison canteen/catalogue services;
- Negotiating access to off-wing activities - e.g. healthcare appointments (routine & acute), church attendance, vocational activity, gym;
- Attendance at off-wing activities;
- Social activities in the wing;
- Use of time in cell;
- Use of prison and healthcare complaints procedures;
- Access to legal representatives and handling of any ongoing criminal matters; and
- Involvement in sentence planning/discharge arrangements.

For participants included in this part of the study, we will aim to observe each of these activities at least once, where applicable, and will record field notes to include details of the place and time of the observation, the setting and details of what happened during the observation.

The details of field notes will vary depending on the events being observed. For example, in the case of contact with healthcare providers, there will be a focus on the interaction itself (where both staff and prison resident have consented to take part). The observation will record details of verbatim verbal interactions as well as non-verbal. This will enable us to record how staff assess and establish the extent of symptoms and problems faced by prisoners, and how any solutions are worked out in practice. We will also record details of any relevant documents that are used to inform management of prisoners with cognitive impairment. For example, are there relevant assessment frameworks or standard operating procedures (SOPs) for how to assess and manage prisoners with such problems. We know from existing work within prisons that some healthcare interactions take place in a public space (e.g. administration of medicines) and we will observe where and how interactions with staff take place, and the degree to which this allows for sufficient attention to specific symptoms and problems experienced by those with cognitive impairment.

In the case of activities in communal spaces, the observer will again focus on consenting prisoners and staff, and the main focus will be on organisational context, and physical space to consider how the environment and material objects within the environment may influence experience for prisoners with dementia. This draws attention to materialities of care (Martin et al, 2015) and attention will be focused on tasks and navigation of the physical environment which may present difficulties for those with impaired cognitive function, such as the examples given above. For example, are people able to follow usual practice in collecting meals, and participating in group activities? Do they become confused or agitated in some environments entailing more complex tasks? What are the circumstances, and where do prisoners with cognitive impairment seem most comfortable and better able to function physically and cognitively? Are there some environments and circumstances where they seem well supported and integrated with others, or are there circumstances where they seem isolated and more confused? The researcher will observe alongside staff working in the specific prison contexts, and no details will be recorded regarding speech or activities of other prisoners or staff that have not consented to take part in the study. Please see the ethics session below for our researcher safety protocol.

After each observation session the researcher will make more detailed field notes expanding short hand into sentences and adding further comments and reflections. These notes will be typed up into a narrative account describing what happened and what the researcher was able to learn about the prisoners' day-to-day experiences. The researcher will differentiate between their perceptions and actual activities that occurred.

iii. Informed Consent

Following the general principles of ethnographic research, we will not individually consent all prisoners on a wing. Instead, accepted practice is to provide some general information to inform prisoners that we are doing an observational study aiming to understand some aspects of prison life, and to understand the management of health problems for some prisoners. Those eligible to be involved specifically in the study will receive further information and their consent will be requested. No details will be recorded during the observations that would reveal identity of prisoners.

With regard to a possible situation where prisoners agree but not their families, the outcome would depend on the individual's capacity, determined using the processes for establishing capacity (in line

with the MCA) already described. If the prisoner has capacity to consent, then their decision should be respected. This is relevant for the ethnography component as it is focused on prisoners, not carers. Similarly, if carers do not wish to be included by taking part in an interview, their decision would be respected.

b. Stage Two: Semi Structured interviews

i. Sample

Semi-structured interviews will be conducted with staff members, other prisoners, friends/family members and carers as well as with the individuals themselves (where possible and appropriate). We will aim to conduct approximately five interviews per individual case study to provide multi-dimensional narratives of the experience of living with cognitive impairment in prison. Where possible, we will ask the prisoners with suspected cognitive impairment/ dementia to specify who they feel would be able to provide a valuable insight into how they manage their needs on a day-to-day basis. We will aim to ask them to identify five people, possibly from each of the groups listed below. Speaking with individuals in different key roles will help us to achieve triangulation of data.

- Prison staff member (e.g. personal officer/senior officer/wing officer)
- Prisoners (e.g. cell mate, carer, cleaner, co-worker)
- Healthcare staff (e.g. health care assistant, nurse, psychologist, psychiatrist, general practitioner)
- Friend/family member (e.g. son/daughter, neighbour, sibling)

We will not contact any family member/friend without the prisoners' explicit written permission. We will also invite the healthcare manager, governor and any other key member of staff who could provide a more strategic/organisational level perspective to participate in semi-structured interviews.

ii. Procedure

Interviews with family members will describe what life has been like for their relative in prison and give a perspective on key events in the pathway to diagnosis, for example how and when problems were first identified; which people were significant in prompting their relative to seek support; and what barriers or facilitators to support have been encountered. Staff members will be encouraged to reflect on their role and responsibilities with this prisoner group in the context of the wider environmental and organisational context in which they work. This will include a critical consideration of their training needs and role/personal confidence and competencies.

The interviews will be audio recorded (with permission). The research team are aware that some prison governors do not permit the use of recording equipment in prisons. Therefore in such circumstances and where possible, the interviews will be held outside of the prison establishment. Where this is not possible (e.g. for interviews with prisoners), two researchers will attend the interview in order to allow one researcher to make detailed notes. The interviews with friends/family members will take place in a mutually convenient and acceptable public location. It is anticipated that the interviews will last between 30 minutes and one hour. If individuals would prefer to conduct the interviews over a number of different occasions then this will be accommodated.

Qualitative Analysis

The qualitative data (transcriptions and field notes) obtained during interviews and observations will be analysed using a framework method. This method produces a matrix of summarised data which

provides a structure to analyse and reduce the data. A key benefit of this approach, in comparison to other forms of thematic analysis, is that the context of participants' data is not lost (Gale et al., 2013). Additionally, the framework method has been selected because it is particularly useful to inform the design of training materials (part 5) as both predefined themes and themes that emerge from the data can be used.

Gale et al. (2013) proposed seven stages for this approach. Stage one involves transcription of the data by professional transcribers. Transcriptions will be produced *verbatim*; however the focus will be on content rather than pauses and tone. During the second stage, the researcher conducting the qualitative element will familiarise themselves with the whole interview. Coding commences at the third stage of the process using QSR International's NVivo 10 qualitative analysis software. Codes will include behaviours, incidents, structures, values and emotions. Stage four involves the development of a working analytical framework. After the initial few transcripts have been coded, a set of codes will be developed and applied to the analysis of all subsequent transcripts. It is anticipated that numerous adaptations will be made to the analytical framework throughout the analysis process until no new themes emerge. The analytical framework will then be applied to all subsequent transcripts using the existing categories and codes during stage five of the analysis. During stage six, framework matrices will be developed in NVivo and data will be charted into the matrices. This will involve summarising the data by category for each transcript. The chart will include references to illustrative quotations. The final stage seven is concerned with interpreting the data.

This part of the study will provide rich data describing the lived experience of dementia in a prison. The data will be incorporated into the vignettes to be developed in part 4 (stage 1) and the training package development in part 4 (stage 5).

Consent/Ethical Issues

Prisoner and staff participants (focused ethnography – direct and indirect participation):

The focus of the observations will be on prison staff, and the individual prisoners with dementia or cognitive impairment sampled from stage 1, where consent has been taken as outlined previously. The direct consent of the specific prisoner being observed will always be sought, ensuring best practice for consenting individuals with cognitive impairment. Similarly, the individual consent of wing staff and healthcare staff dealing directly with the prisoner is sought. We will ensure that we are only recording details from observations concerning these consented individuals, and we have been informed by NOMs that this is the assurance required for ethical approval of the study. No field notes will include any detail of actions, speech, or interactions with staff or other prisoners who have not provided consent.

Posters will be displayed on the residential wing where the individually-consented prisoner lives, stating the purpose of the research and dates of researcher visits, giving prisoners the ability to opt out verbally with researcher. With regard to observations in areas other than the wing, similar posters will be displayed in all other parts of the prison the consented individual prisoner may visit e.g. library, gym, education, chapel allowing verbal opt out for prisoners, accompanied by verbal opt out for staff if no real concerns are raised or formal consent from staff if anyone has any major concerns; this will be established and agreed/completed during project set-up.

Specific individual consent will be sought from any prisoner who has a more formal, rather than just passing, interaction with the subject i.e. a peer carer/buddy/mentor etc. and where a "passing" interaction with the individual by another prisoner becomes a potentially more meaningful/in-depth

interaction likely to be referred to in detail in the research, consent from the second prisoner to include the data will be sought *post hoc*.

Prisoners' carers and family members (semi-structured interviews):

Prisoners' carers and/or family members will only be approached with the consent of the prisoner participant. If the prisoner lacks the capacity to consent to their family being contacted, no such contact will be made by the research team. Informed consent will be sought from all family members/carers prior to their participation.

Prior to contacting anyone outside of the prison for potential participation, researchers will liaise with the prison healthcare SPOC to establish whether the individual's family are aware of their suspected cognitive impairment. If family members are not aware, then, even with the individual's permission to contact them, researchers will not take any action before consulting with the healthcare SPOC to agree a course of action. The course of action taken will be led by the healthcare SPOC and based on agreed procedures for contact with family members. (For example, during prison healthcare reception screening, prisoners are asked to identify a next of kin and indicate whether they are happy for them to be contacted regarding their healthcare). It is very important that we avoid upsetting family members or friends who may not be aware that there are any concerns about the individual taking part in the study.

7. Study Part Four

a. Stage One: User profiling.

The key characteristics, including social care needs, risk (of harm and reoffending and co-morbidity of prisoners with cognitive impairment in the part 1 prisoner sample dataset will be identified using descriptive analysis. A selection of these variables will then be used to divide the sample into relatively homogeneous subgroups known as '*case types'* i.e. groups of prisoners with similar needs for health and social care. The attributes used to form these categories will be identified via a combination of exploratory (latent class and multivariable) analyses of the prisoner dataset; a review of the prisoner literature; and consultation with prison and health and social care staff, prisoners and their family/friends in parts 2 and 3. Possible attributes include measures of prisoners' age; severity of cognitive impairment; need for help with activities of daily living and safety; and healthcare needs associated with co-morbid long-term conditions. A series of vignettes will be formulated to represent these case types. These will be based on fully anonymised exemplar cases in the prisoner dataset and will take the form of short case histories. The vignettes will be drafted with the help of a group of experienced local authority and prison care staff, who will also proof read the final versions to ensure their content validity (Challis et al., 2013, 2014). This group of individuals will also comment upon draft versions of the training package (stage five).

In developing the case vignettes, great care will be taken to ensure that the details of each case do not allow identification of any individual. For example, each case vignette will not describe any one individual in detail but will include characteristics observed from multiple individuals within a certain typology blended into a representative case description.

b. Stage Two: Service identification.

A range of managers from local statutory social services, NHS England regional health in criminal justice leads, community social workers, prison healthcare staff, older adult psychiatrists,

commissioners, service users, carers, geriatricians and representatives from specialist older adult organisations and charities will be invited to take part in a care planning workshop at which the most appropriate way to meet the health and social care needs of the prisoners depicted in the above vignettes will be explored. In order to maximise attendance, workshops will be held in three different regions of the country, thus allowing the inclusion of staff working in each type of prison – women, high secure, local, training and open.

i. *Sample*

We will recruit between 12 and 16 individuals to each workshop (total target sample size 36-48). Based on past experience, this will enable us to harness the skills and experiences of people from a variety of backgrounds and attract sufficient staff for each vignette to be reviewed by at least three small groups. It is also important that the care-planning workshops and later validation workshops involve a critical mass of those key stakeholders who will subsequently need to implement any service change.

ii. Procedure

Recruitment

Managers and clinicians within each relevant local authority, prison and provider healthcare trusts will be asked to identify members of staff with relevant knowledge and experience who might be willing to contribute to the research. Individuals will be given an invitation letter and participant information sheet by their manager and asked to contact a nominated member of the research team. Individuals who are happy to participate will be asked to sign a consent form.

Workshop format

Each care-planning workshop is expected to last approximately 90 minutes and will involve two activities. First, workshop participants will be divided into small groups of three or four people, each of which will be given a subset of pre-selected vignettes. They will be asked to explore and describe the kinds of services required if the person was in living in the community. Second, participants will use the information summarised from parts 2 and 3 of the study to examine service need specifically within prisons and how provision would need to be adapted from the community.
The workshops will be audio-recorded.

iii. Data analysis

The audio recordings from the group discussions will be transcribed verbatim and thematic analysis will be conducted to identify participants' attitudes and values in relation to the service eligibility and delivery issues explored using the framework method described above. This method is appropriate as it allows pre-defined themes to be included, in addition to themes which are derived from the data. A detailed description of the recommended care pathways will be produced.

c. Stage Three: **Service validation.**

Validation workshops will be held with relevant local-authority managers and prison care staff to explore the above findings and their implications. The care pathways previously developed will be validated. If possible the workshops will be linked to routine meetings held by these stakeholders, so reducing demands upon busy participants.

i. Sample

The exact number of people who will attend each session is likely to be between 8 and 12. We envisage holding 2/3 workshops. As with the care-planning workshops, the important consideration is that the exercise harnesses the knowledge and experience of a range of key players with different backgrounds, experiences and interests.

ii. Procedure

Recruitment

The Chairs of established staff groups will be approached with a view to the research team attending an appropriate meeting to present their findings and receive feedback. Group members will be sent an invitation letter and Study Information Sheet about the planned activity in advance of the routine meeting at which the findings will be presented. These will be formulated by the research team, but distributed by the groups' Chairs, and will make it clear that participation in these sessions is entirely voluntary and any individual can opt out of this part of the meeting without giving a reason. To facilitate this, it is anticipated that these sessions will precede or follow the meetings' routine agendas. Individuals who are happy to participate in the workshops will then be asked to complete a consent form.

Workshop format

Each validation workshop is expected to last approximately 75 minutes and will mirror the format used in two previous balance of care studies completed by the research team. Thus, further to a presentation of the findings from the care-planning workshops, participants will be invited to comment on the validity, veracity and viability of the results, and to identify the potential impact and implications of the proposed care arrangements from their particular perspective in a whole group discussion. This exercise is designed to enhance understanding of the challenges and enablers of effective service provision and to distil the key features of an appropriate service response. With the consent of all participants, the discussions will be audio-recorded. This approach to translating individual needs into service needs and care pathways is novel in prison settings but the methodology proposed has been previously.

iii. Data analysis

The audio recordings from the group discussions will be transcribed and analysed using the framework method as for the care-planning workshops**.**

d. Stage Four: Cost projection.

The resources needed to provide the elements of each care pathway validated in stage 3 will be identified by the panel of experts and the annual cost of providing each care pathway will then be estimated by applying the unit costs in criminal justice produced by the Personal Social Services Research Unit to the resources identified (Brookes et al., 2013). These costs estimates will then be combined with the matrix of prevalence estimates produced in part 1 stage 3 to perform a budget impact analysis (BIA) of the costs of implementing the recommended care packages nationally. The various prevalence scenarios produced will be used to present a range of cost estimates, following the ISPOR task force principles of good practice for BIA (Mauskopf et al., 2007, Sullivan et al., 2014). Finally, the service provision data from the care-planning exercise will be entered into an excel-based cost-modelling template developed by the research team, to enable each prison site/commissioner to estimate their own projected costs given their populations.

e. Stage Five: Development of Training materials for prison based health and social care staff and prison officers

In part 2 and part 3, we will establish the current state of play as regards staff training on the assessment and care needed for older prisoners with cognitive impairment and dementia, gaps in this training and training format preferences. We will design training materials to support a range of staff in developing the key competencies and confidence required to deliver high quality care and support in the proposed care pathways developed in part 4. Although the actual content of the training will be informed by the study, the training will be based on an examination of "*what works*" across the wider training intervention literature (Salas & Cannon-Bowers, 2001; Salas et al., 2012) incorporating methods with evidence of effectiveness such as roleplay and modelling (Salas & Cannon-Bowers, 2001.). Social Cognitive Theory (Bandura, 1977; Bandura 1997), with its emphasis on social learning and self-efficacy on learning and behaviour will be drawn on to inform the development of the training. Similarly, the Theoretical Domains Framework (Cane, O'Connor & Michie, 2012; Michie et al., 2005), the behaviour change technique taxonomy (Michie et al., 2013) and a framework developed by co-applicant KP for the design of optimal training (Perryman, 2014) will be used for developing strategies for effective implementation of evidence based practice. We will use data from Part 2 to elicit staff preferences for style of training and utilising the theoretical constructs we will design the training and then utilise our practitioners from part 4, stage 1 and 2 to provide views on relevance and acceptability of the training. A training manual will be developed by researchers in conjunction with these practitioners.

8. Data Storage and Protection

All data will be stored and processed in line with BS ISO/IEC 27002 2005 and the Data Protection Act.The security of personal data is ensured by the Information Security and Management Policy of the National Confidential Inquiry (as the research team are based on the same corridor) and the System Level Security Policy for the Centre for Mental Health and Safety. Procedures to ensure appropriate security measures for computerised and manual personal data are set out in these policies. Amongst other things this sets out protocols for: a) information handling and storage, b) regular data backup to protect against information loss, c) risk review, d) disaster recovery policy and e) restricted access to identifiable data.

All hard copy data will be stored in locked filing cabinets in a secure office located on a secure corridor and will only be made accessible to the research team. The use of keys is restricted to those members of staff who require them and staff are required to sign for keys.

All electronic data will be stored on password protected systems in a secure office and will only be made accessible to the research team as necessary. Participants' personal details will be stored in separate locked filing cabinets (hard copies) or on secure, password protected, internal systems (electronic copies) in a secure locked office. The Inquiry's internal network cannot be accessed by external servers and therefore is only accessible by individuals registered to do so and their access is restricted. All computers are encrypted and password protected.

University staff are forbidden from transferring personal information from University computer systems, (e.g. email), to any other device that is not registered with the Centre, including CDs; floppy or hard disks; tablets; laptops; USB memory modules or any other storage media or device. Where data must be transferred onto a portable device, the device must be registered with the Centre and

must meet therefore must meet the associated requirements for password protection and encryption. The university use Truecrypt, an AES 256 encryption algorithm.

The information in the study will be bound by the Confidentiality Policy which forms part of the Information Security and Management policy. Confidentiality clauses are included within all staff contracts and staff are made aware of their responsibilities.
The research team will collect identifiable data (name, date of birth and prison number) but these data will not be used in the analysis or publication of findings. Identifiable data will be stored securely and separately from outcome data. A personal identifier (a three-digit number), will be used to link the identifiable and non-identifiable data. The identifier key will also be stored securely and separately from outcome data. Other personal data pertaining to participants' self-reported criminal justice history, mental and physical health, sensory or learning difficulties and use of substances and/or medication will also be collected. However, these data will only be published as overall sample descriptives, so no individual will be identifiable.

Publications of direct quotes from respondents will be anonymised. The final report and any subsequent publications will be thoroughly checked before publication to ensure anonymity.

9. Potential Risks and Burdens

The research team are experienced in working within the dynamic prison environment. During two recent, prison-based RCTs, recruitment was affected by sites changing their role/population-type (gender, age, security category) and delays were encountered when healthcare contracts changed to new providers. In order to meet targets, new sites were recruited, which was a lengthy process. In the proposed study, this would only affect recruitment in part 1. However, we will mitigate against this by recruiting more sites than the minimum needed to meet data collection targets from the outset. Recruitment targets and timeframes have all been calculated allowing sufficient contingency for known barriers in secure environments, e.g. lockdowns (meaning that no prisoners can be seen at all during a given time). KF, JJS and JS are all experienced in the ad-hoc problem-solving required to collect data in prisons and are therefore well-placed to support researchers in meeting targets.

Researchers will at all times be guided by the clinical staff as to the appropriateness of data collection regarding offender interactions and participant selection for interviews and observations. Nevertheless, there is a possibility that participants may experience discomfort or become distressed, not least because of the sensitive nature of the questioning in an area where they may be having difficulties. Interviews will be carried out by experienced researchers. During interviews researchers will be aware of the sensitivities of some of the questions and carefully choose their approach and take account of the priority for comfort and ease of the participant. Regular research meetings between the fieldworkers and the senior researchers will include reflection on data collection processes and one-to-one supervision to provide a safeguarding basis and identifying changes to procedures if needed. The clinicians within the research team will be available to guide researchers throughout data collection and an individual from the healthcare team at each site will act as a single point of contact (SPOC) for field researchers.

Prior to discussion, information sheets including ethical rights and outlining the content of the interviews will be given to participants to help prepare them and minimise risks/burdens as far as possible. Should a patient become distressed through interview the researcher will do their best to calm the situation and leave if necessary. Researchers will have appropriate training to aid them in this decision. If the prisoner participant is significantly upset, the researcher will, with their permission, let appropriate health care or prison staff members know and will encourage the prisoner to seek the

further support that is available in their environment. Resources in the prison include the healthcare team, the prison listener system, and the chaplaincy team.
The consent process will make it very clear that if a participant tells the researcher that they intend to harm themselves, someone else, or threaten the security of the prison, then confidentiality will be broken and relevant services will be informed immediately.

10. Ethical issues

We have worked closely with offenders and prison/practitioner representatives in previous similar projects and this has helped us to develop the protocol and discuss the ethical issues relating to collecting data in prison settings. In particular we have discussed issues relating to consent to ensure that processes are feasible and acceptable. We are also aware of the time constraints on prison staff and that the research may place additional stress on them in an already challenging environment.

a. Voluntary nature of participation

   Information sheets for participants will make it clear that participation in the study is voluntary. No undue pressure will be placed on potential participants to take part in the research, either by the research team or by prison or healthcare staff. It will be made clear to participants that their decision to accept or decline to take part in any part of the research will not affect the care they receive or their other legal rights.

b. Informed Consent

   i. Prisoner participants

      All potential participants will be provided with an information sheet outlining what participation in the study will involve and how data will be used. The study information sheets have been reviewed by ex-older prisoners via the RESTORE support network and by service users diagnosed with cognitive impairment at a local memory clinic for older adults. All participants will be required to give their formal, informed consent before any data is collected. Participants will be given sufficient time to consider the information provided and ask questions, prior to providing consent. All researchers will have had practise and training in obtaining informed consent.

   ii. Prisoner participants lacking capacity

      Given the nature of the main research question, it is important that we do not exclude individuals who lack the capacity to provide informed consent due to cognitive impairment or dementia. In line with the requirements of the Mental Capacity Act, Section 31(2005), there are reasonable grounds for believing that research of comparable effectiveness could not be carried out if the sample was confined to adults with capacity and there is clear potential to benefit both participants and individuals in the future with the same/similar impairing condition.

      Where researchers have concerns that an individual lacks the capacity to provide informed consent, they will follow the steps of the process consent method (Dewing, 2007) and will proceed in line with the MCA (2005), as outlined previously.

c. Identification of Cognitive Impairment/Dementia

It is possible that during part one of the study, individuals may be identified as having a degree of cognitive impairment or lacking capacity. If this happens, researchers will follow a procedure as agreed with each site to notify prison healthcare staff in the best interests of the participant or potential participant. Where researchers identify concerns, they will ask the participant for their permission to make healthcare staff aware of the basis for their concerns. However, if researchers have concerns which place the individual or anyone else at risk of harm, they will notify healthcare and wing staff without seeking permission. This process will be detailed in the participant information sheet and therefore made explicit to individuals prior to participation. The precise method of communicating this information and timescale within which it should be communicated, will be agreed with each site during set-up. However, where there are concerns of imminent risk, researchers will ensure that information is passed on as quickly as possible and certainly before leaving the site.

d. Safety of Researchers

Researchers will be meeting prisoners within the prison environment, where they will follow all of the local security arrangements, procedures and policies, as advised by the prison and adhere to the University of Manchester's lone working policy. Researchers will undertake a security awareness induction and personal strategies training, as required by each prison. This training covers health, safety and security procedures as well as anti-corruption and physical breakaway techniques. Within the prison, researchers will adhere strictly to local procedures, in line with their training and will be guided by prison staff at all times, given the dynamic risks within the environment. Interviews will take place in rooms fitted with alarm systems and where possible, researchers will carry personal alarms. Researchers could become emotionally fatigued from listening to the difficulties faced by other people in what can be a challenging research environment. They will therefore be encouraged to debrief to lead members of the research team and to each other, when appropriate. Lead research team members will also proactively review researchers' emotional wellbeing throughout the course of the study.

11. Project Management

Independent Steering committee: An independent study steering committee (SSC) will be created to provide overall supervision for the project. In line with the NIHR guidelines, it will focus upon the progress of the study, adherence to the protocol, participant safety and will consider any new information relevant to the research question. We will aim to ensure that the membership of the SSC will include an independent chair, a statistician, a health economist, service users and/or carers as well as individuals with relevant experience of clinical practice and prison environments. Representatives from the project sponsor and the funder will also be invited to all SSC meetings. The SSC will meet at least annually but will meet more frequently if required.

Project Management Group: All members of the research team will sit on the Project Management Group tasked to ensure that project milestones are met and expenditure is appropriate within available funds. Meetings will be scheduled so as to best inform the different stages of the research and provide the researcher with timely guidance. It is envisaged that the Steering Group will meet at least twice a year.

12. Patient and Public Engagement

Dr Stuart Ware is a co-applicant; an ex-older prisoner; and founder member of the group Restore Support Network ([RSN] a registered charity for older prisoners). His involvement ensured that we considered the needs of older prisoners throughout the development of this proposal. The Peer

Research Group within RSN, also assisted in the development of this application. The group comprises four ex-prisoners who have been trained in research methods by Dr Ware. The group welcomed the research, indicating that it will help to fill a gap in knowledge and help shape service development. They had experience of supporting other prisoners with dementia and highlighted the impact of having cognitive impairment in prison e.g. behaviour such as forgetting to turn up for appointments being mistaken for disobedience. They commented on drafts of this application and it has been adapted accordingly. In particular, they co-wrote the plain English summary. They have also provided useful additions to the design, such as ensuring the care pathways developed considered services on release from prison, linking into other relevant care pathways.
Dr Ware will sit on the steering group; be involved in the management of this research study; and will provide his expertise responsively throughout the life of the project. This will ensure the perspectives of older prisoners are considered throughout. Two service users will be recruited to sit on the panel of experts which forms a key part of the methodology for this study. The panel will be responsible for developing pathways to care for those with cognitive impairment and for dementia in prison and staff training packages. The Peer Research Group at the Restore Support Network will assist in the development of participant information sheets and newsletter style reports to be distributed to prisoners to inform them about the findings of the research. They will also participate in presentations to disseminate the research to commissioners, prison and healthcare staff. Dr Ware completed his PhD on the needs of older prisoners and has experience of supporting and training ex-service users. Support provided to the group will be tailored to their developmental needs, throughout the project, in consultation with INVOLVE workers.

In addition, a post-diagnostic dementia support group will be asked to assist in the development of information sheets, consent forms etc. to ensure the needs of individuals with cognitive impairment and dementia are considered.

13. Dissemination

A comprehensive strategy will be employed to ensure that findings are disseminated to a wide range of professional and service user audiences. As a team we are ideally placed to ensure that our research impacts upon front-line practitioners and is embedded into future policy. The chief investigator for the proposed research is the academic lead for the Offender Health Research Network (OHRN) which is a multi-disciplinary and multi-agency network with over 2,000 members, including health and prison staff. The research will be disseminated via the OHRN website and monthly newsletters and all training materials will be made freely available. As National Clinical Director for Dementia, AB is in an excellent position to promote the research as part of his role. We also have a letter of support from Nick Hardwick (Chief Inspector of Prisons, National Offender Management Service) who has had input into the study design and is well placed to publicise the findings. Publications will be submitted to peer reviewed journals to disseminate the findings to academics and practitioners and we will present at relevant conferences. The research team will work alongside the Peer Research Group at the Restore Support Network to develop newsletter style reports, ensuring accessibility to serving prisoners. The Peer Research Group will inform the research team on how best to disseminate these.
Representatives from all prisons and healthcare trusts providing services within prisons in England and Wales will be invited to an end of study conference to disseminate the findings. Where findings relate to specific prisons, including those participating, this information will be imparted via presentations and/or tailored reports. We will liaise with the specific prisons in question to establish which modes of dissemination would be preferable. In addition, the Peer Research Group and the research team will disseminate the findings and the training pack at workshops in each of the four commissioning group regions (North, Midlands/East of England; London; and the South of England) with a view to hold subsequent 'train-the trainer' sessions and evaluate the pack. The report will

summarise the evidence and draw out implications for practice for the NHS, Government, HM Prison Service and local authorities. The report produced will indicate clearly which group or groups each recommendation is targeted at, to assist with issues of accountability and clarity.

Outputs from the proposed research will include:

1) Publication in Journals such as the British Medical Journal, the British Journal of Psychiatry, Age and Ageing, Dementia and The Prison Service Journal. We will ensure we include open access journals to extend the readership;
2) Best practice booklets for prison staff and staff working in partner agencies such as probation services, Age UK, Alzheimer's Society, Dementia UK, and other voluntary organisations;
3) Report and associated training materials for practitioners, managers, policy leads and academics;
4) Newsletter style report for prisoners/ex-prisoners;
5) Conference presentations (these will be conducted at The International Association of Forensic Mental Health Services Conference, The Agenda for Later Life Conference (Age UK) and other timely, relevant conferences);
6) Workshops for prison staff, NHS staff, local authority practitioners and mangers as well as policy leads at each of the four regional commissioning groups;
7) Presentations/reports for individual prisons participating in the research;
8) Training pack for prison and healthcare staff;
9) A webpage will be developed by the research team (as part of the OHRN website).

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