We need to talk about dementia: The role of stigma and the social network in preventing help seeking for a diagnosis of dementia

Volume II

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Appendix 1 Phase 1 - PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	73 & 111
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	116
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	116-118
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	75 & 118
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	73/ 118 & Appendix 4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	75-76
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	76 & 118
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	77 & 118-119

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	77 & 118-119
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Appendix 2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	78 & 119
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	78-79 & 119
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	146-147
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
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Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	132-133
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
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Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	121
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FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

Appendix 2 Phase 1 - PROSPERO Registration

PROSPERO

International prospective register of systematic reviews

The factors that influence people with dementia and/or their carers to seek help for a diagnosis of dementia. A systematic review

Michelle Parker, Sally Barlow, Juanita Hoe, Leanne Aitken

Citation

Michelle Parker, Sally Barlow, Juanita Hoe, Leanne Aitken. The factors that influence people with dementia and/or their carers to seek help for a diagnosis of dementia. A systematic review.

PROSPERO 2018 CRD42018092524 Available from:

http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018092524

Review question

1. What are the perceived barriers or reasons for a delay in help seeking to obtain a diagnosis of dementia?

2. What are the perceived facilitators to help seeking for a diagnosis of dementia?

Searches

The electronic databases CINAHL, MEDLINE, PsycARTICLES, PsycINFO and SocIndex will be searched through EBSCOhost one database at a time and the electronic database EMBASE will be searched through OVID Online. Grey literature will be searched using the databases BASE and OpenGrey. The search strategy will include keywords related to the population (dementia or Alzheimer's disease) the concept of help seeking and barriers, delays, facilitators and enablers to help-seeking. Subject heading terms will be used and modified as required for the different databases. Additional relevant papers will be sourced from the reference lists of eligible articles. Searches will be restricted to English language publications only (for pragmatic reasons). No date limits will be place on the search.Example of search strategy for MEDLINE:

MeSH: Dementia/Diagnosis OR Frontotemporal dementia/ Diagnosis OR Vascular dementia/Diagnosis OR Dementia Multi infarct/ Diagnosis OR Alzheimer Disease/Diagnosis OR Lewy Body Disease/ Diagnosis OR memory disorders/Diagnosis OR Cognitive dysfunction/Diagnosis OR Cognition disorders/Diagnosis OR Neurocognitive disorders/Diagnosis OR Confusion/Diagnosis

OR

Keywords in abstract: Dement* OR Alzheimer* OR "vascular dement*" OR "multi infarct dement*" OR "Lewy bod*" OR "memory disorder*" OR "memory problem*" OR "cognit* disorder*" OR "neurocognit* disorder*" OR confus* OR forgetful*

AND

MeSH: Help-seeking behaviour

OR

Keywords in abstract: “help seeking” OR “help-seeking” OR seek* OR access* OR delay* OR avoid* OR barrier* OR obstacle* OR facilitat* OR enable* OR trigger*

AND

MeSH: Delayed diagnosis OR Diagnosis OR Early Diagnosis

OR

Keywords in abstract: diagnosis OR “early diagnosis” OR “delay* diagnosis” OR “late diagnosis” OR undiagnosed OR undetected

Types of study to be included

It is expected that qualitative, quantitative and mixed methods studies will address the review question so primary research studies of all designs will be included in the review.

Condition or domain being studied

This review will focus on the time before a diagnosis of dementia and the factors that people with dementia

and/or their carers believe delay or facilitate seeking help for a diagnosis of dementia.

Participants/population

Inclusion: people with dementia (any subtype), carers of a person with dementia (any subtype) e.g. an adult family member or friend who gives unpaid support to the person with dementia and regards themselves as a carer.

Exclusion: lay public, health care professionals.

Intervention(s), exposure(s)

Help seeking for a diagnosis of dementia.

Some studies focus on help seeking for care, management and support in dementia. Studies for inclusion in this review must include a focus on help seeking for a diagnosis. Help seeking in this sense can be defined as, “Problem focused, planned behaviour involving interpersonal interaction with a selected health care professional” with the intention of disclosing a problem in exchange for help (Cornally et al 2011).

Comparator(s)/control

Not applicable

Context

This review will focus on studies of the actual help seeking behaviour of people with dementia and their carers prior to diagnosis. It will exclude studies which focus on help seeking intentions or attitudes and those which focus solely on the perspectives of the lay public or health care professionals. Only studies reporting factors related to help seeking for a diagnosis of dementia will be included. Where factors related to help seeking for a diagnosis are reported alongside factors influencing help seeking for care, management or support, studies will only be included if the factors related to diagnosis help seeking can be clearly differentiated from other help seeking.

Primary outcome(s)

Perceived barriers and facilitators to help seeking for a diagnosis of dementia.

Secondary outcome(s)

None

Data extraction (selection and coding)

Study selection

Stage 1: Titles and abstracts of studies retrieved from the search will be screened independently by two members of the review team to identify studies that meet the inclusion criteria and could potentially be included in the review.

Stage 2: The full text of articles deemed potentially eligible will be obtained and independently assessed by two members of the review team for inclusion. Any disagreement over the eligibility of a study for inclusion will be resolved through discussion with a third reviewer.

Data Extraction

A pre-piloted form will be used to extract data from the included studies which will include: author, year and geographical location of study; methodology; sample size and recruitment; participant characteristics (people with dementia); participant characteristics (carers); data collection methods; data analysis methods; reported barriers or facilitators to help seeking; data related to risk of bias assessment. One member of the review team will extract data from all included studies. A second member of the review team will check for accuracy on 25% of the included studies. Any disagreements will be resolved through discussion with a third member of the review team.

Risk of bias (quality) assessment

Critical appraisal of included studies will be conducted using the Mixed Methods Appraisal Tool (MMAT) to assess the quality of included studies (Pluye et al 2011). The tool was designed to be used in complex systematic reviews that include qualitative, quantitative and mixed methods studies. It includes a section of four questions to consider for qualitative studies and three sections of four questions for quantitative studies (one for RCT's, one for non-randomised studies and one for descriptive studies) to be used as applicable. For mixed methods studies the questions in the qualitative section and the appropriate quantitative section should be applied to the appropriate part of the study and then an additional three questions regarding the mixed methods component of the study are applied. Two members of the review team will be independently appraise each included study and any disagreements will be resolved through discussion with a third member of the team.

Strategy for data synthesis

It is expected that there will be a mix of qualitative, quantitative and mixed methods studies included in this review. The review intends to use a mixed studies synthesis design proposed by Pluye & Hong (2014), a convergent qualitative synthesis, to integrate findings from all studies. Using a qualitative thematic synthesis technique, data from all studies will be transformed into qualitative themes. Using an inductive approach one member of the review team will derive themes from the data, going back and forth from the data to the themes following discussion and consensus with other review team members as necessary. A narrative approach will be used to synthesise data within themes and to explore relationships within and between the themes identified.

Analysis of subgroups or subsets

Analysis of themes related to subgroups (e.g. people with dementia, carers, by country or ethnic group) may be undertaken but this will depend on the scope of included studies and cannot be specified in advance.

Contact details for further information

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Organisational affiliation of the review

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Review team members and their organisational affiliations

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Professor Leanne Aitken. City, University of London

Anticipated or actual start date

01 March 2018

Anticipated completion date

01 September 2018

Funding sources/sponsors

City, University of London

Conflicts of interest

Language

English

Country

England

Stage of review

Review_Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Caregivers; Dementia; Humans; Perception

Date of registration in PROSPERO

04 April 2018

Date of publication of this version

04 April 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

Stage

Preliminary searches Yes

Piloting of the study selection process No

Formal screening of search results against eligibility criteria No

Data extraction No

Risk of bias (quality) assessment No

Data analysis No

Versions

04 April 2018

Appendix 3 Phase 1 - Full search strategy used for Medline database

Search no.	Search terms
S1	(MH "Dementia/DI") OR (MH "Frontotemporal Dementia/DI") OR (MH "Dementia, Vascular/DI") OR (MH "Dementia, Multi-Infarct/DI") OR (MH "Alzheimer Disease/DI") OR (MH "Lewy Body Disease/DI") OR (MH "Memory Disorders/DI") OR (MH "Cognitive Dysfunction/DI") OR (MH "Cognition Disorders/DI") OR (MH "Neurocognitive Disorders/DI") OR (MH "Confusion/DI")
S2	AB dement* OR AB Alzheimer* OR AB "vascular dement*" OR AB "multi infarct dement*" OR AB "lewy bod*" OR AB "memory disorder*" OR AB "memory problem" OR AB "cognit* disorder*" OR AB "neurocognit* disorder*" OR AB confus* OR AB forgetful*
S3	(MH "Help-Seeking Behavior")
S4	AB "help seeking" OR AB "help-seeking" OR AB seek* OR AB access* OR AB delay* OR AB avoid* OR AB barrier* OR AB facilitat* OR AB enable* OR AB trigger* OR AB obstacle*
S5	(MH "Diagnosis") OR (MH "Delayed Diagnosis") OR (MH "Early Diagnosis")
S6	AB diagnosis OR AB "early diagnosis" OR AB "delay* diagnosis" OR AB "late diagnosis" OR AB undiagnosed OR AB undetected
S7	S1 OR S2
S8	S3 OR S4
S9	S5 OR S6
S10	S7 AND S8 AND S9

Appendix 4 Phase 1 - Data extraction form

Title Author Year Country
Study aim/ research question
Study design/ method (inc philosophical approach if appropriate)
Sampling approach
Sample size and participant type
Participant characteristics
Confirmation of diagnosis
Data collection method (including relevant questions asked if included)
Analysis approach
Key themes/ data related to barriers with quotes/ examples
Key themes/ data related to facilitators with quotes/ examples
Author interpretation of data
Recommendations by authors

Appendix 5 Mixed Methods Appraisal Tool and application to this study

Category of study designs	Methodological quality criteria	Yes	No	Can't tell	Comments
Screening questions (for all types)	S1. Are there clear research questions?	X			P58-59 Ch 7 & 8
	S2. Do the collected data allow to address the research questions?	x			
	Further appraisal may not be feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening questions.				
1. Qualitative	1.1. Is the qualitative approach appropriate to answer the research question?	x			P79
	1.2. Are the qualitative data collection methods adequate to address the research question?	x			P86-89/ Ch 5
	1.3. Are the findings adequately derived from the data?	x			Ch 5
	1.4. Is the interpretation of results sufficiently substantiated by data?	x			Ch 5
	1.5 Is there coherence between qualitative data sources, collection, analysis and interpretation?	x			Ch 5
2. Quantitative randomized controlled trials	2.1 Is randomization appropriately performed?				
	2.2 Are the groups comparable at baseline?				
	2.3 Are there complete outcome data?				
	2.4 Are the outcome assessors blinded to the intervention provided				
	2.5 Did the participants adhere to the assigned intervention?				
3. Quantitative non-randomized	3.1. Are the participants representative of the target population?				
	3.2. Are measurements appropriate regarding both the outcome and exposure/intervention?				
	3.3. Are there complete outcome data?				
	3.4. Are the confounders accounted for in the design and analysis?				
	3.5 During the study period, is the intervention/exposure administered as intended?				
4. Quantitative descriptive	4.1. Is the sampling strategy relevant to address the research question?	x			P96-97
	4.2. Is the sample representative of the target population?	x			P95/ 203
	4.3. Are measurements appropriate?	x			P97-98 & App 15
	4.4. Is the risk of nonresponse bias low?	x			P202

	4.5 Is the statistical analysis appropriate to answer the research question?	X			Ch 6
5. Mixed methods	5.1. Is there an adequate rationale for using a mixed methods design to address the research question?	x			P61-63
	5.2. Are the different components of the study effectively integrated to answer the research question?	x			Ch 7
	5.3. Are the results adequately brought together into overall interpretations?	x			Ch 7
	5.4. Are divergences and inconsistencies between quantitative and qualitative results adequately addressed?	x			Ch 7
	5.5. Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?	x			App 3, 6 & 14

Appendix 6 Phase 2 - Consolidated criteria for reporting qualitative studies (COREQ)

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	P89 /161
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	Not reported
3. Occupation	What was their occupation at the time of the study?	P229-231
4. Gender	Was the researcher male or female?	Not reported
5. Experience and training	What experience or training did the researcher have?	P231
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	P89 /161
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	P89
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	P229-231
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	P65-73 /160
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	P83-87 /160
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	P83-84 /161
12. Sample size	How many participants were in the study?	P162
13. Non-participation	How many people refused to participate or dropped out? Reasons?	P84-87/ 161
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	P89/ 161
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	P161

16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	P162
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix 12
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	P161
20. Field notes	Were field notes made during and/or after the inter view or focus group?	P90
21. Duration	What was the duration of the inter views or focus group?	P161
22. Data saturation	Was data saturation discussed?	P94-95/ 161
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	P91/ 161
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	P161
25. Description of the coding tree	Did authors provide a description of the coding tree?	No
26. Derivation of themes	Were themes identified in advance or derived from the data?	P161
27. Software	What software, if applicable, was used to manage the data?	P161
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	P164-193
30. Data and findings consistent	Was there consistency between the data presented and the findings?	P164-177
31. Clarity of major themes	Were major themes clearly presented in the findings?	P164-177
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	P164-177

Appendix 7 Phase 2 - Information sheet given to and discussed with psychiatric liaison team staff at team meeting

The timeliness of receiving a dementia diagnosis during an acute hospital admission: the perspectives of people with dementia and carers of people with dementia.

Background

In the UK there are around 800,000 people living with dementia. However only around two thirds of people ever receive a formal diagnosis. Research has shown that there are a number of reasons why people don't seek help for signs of dementia, including thinking that memory problems are part of normal ageing and that there is nothing that can be done to help.

Receiving an early diagnosis of dementia – that is, early in the disease process before symptoms progress - is often thought to be important. But there are pros and cons to receiving an early diagnosis. Increasingly it is recognised that we should be aiming to provide a timely diagnosis – that is, at the right time for the person. However there is little agreement as to what "timely" really means and how people with symptoms of dementia and their families or carers decide when the "right time" is to seek a diagnosis.

Health care professionals in acute hospitals have been encouraged over the last few years to identify people who may have signs and symptoms of dementia when they are admitted to hospital for other physical problems. This can sometimes result in the person being given a diagnosis of dementia during their hospital admission. As these people have not usually sought help for their signs of dementia before being admitted to hospital, we do not know if receiving a diagnosis of dementia during their hospital admission comes at the right time for them.

Overview of the study

This study aims to explore the timeliness and meaning of receiving a dementia diagnosis during an acute hospital admission, from the perspective of people with dementia and from the perspective of families/ carers of people with dementia. To achieve this I aim to interview 5-6 people who have been diagnosed with dementia during an acute hospital admission and 5-6 carers of people who have been diagnosed during a hospital admission. They will each be interviewed twice. The first interview will take place in the few weeks after they have been discharged from hospital. This will be to explore whether they think the diagnosis has come at the right time for them and their reasons for not seeking help prior to their hospital admission. The second interview will take place 3-6 months later and will aim to explore if their thoughts about the diagnosis have changed and whether they would consider it to be timely or not.

The results of this study will help us to understand the process people go through when deciding whether or not to seek help for signs of dementia and whether receiving a diagnosis when you are not seeking help could be considered timely. This could help us in future to support people to access help that leads to a diagnosis at the right time for them. This may mean improving access to services so that people can seek help earlier in the disease process or by providing alternative support for the person until they are ready to be assessed and receive a diagnosis.

Your role in the study

Barts Health will be a participant identification centre for this study. This means that the people who take part in the study will be approached about the study and given information about the study whilst they are inpatients at Barts Health. But the consent for the study and the interviews will take place after they have been discharged from hospital.

The lead nurse for Dementia and the Research and development department at Barts Health have agreed that the Dementia and Delirium teams can approach people during their hospital admission to introduce the study to them.

The study will have received full ethical approval before you start approaching patients/ carers about it. This will include approval of the letters and information leaflets you will give to people.

The recruitment process

1. When you have been informed that a patient in hospital has been given a diagnosis of dementia you will decide whether they and/ or their carer meet the criteria to be involved in the study. The inclusion criteria is:

INCLUSION CRITERIA People with Dementia:

- People of any age diagnosed with dementia, of any sub type, during an acute hospital admission to Barts Health NHS Trust
- Have been informed of their diagnosis during their hospital stay
- Have a named informal carer or next of kin
- Able to give consent or have a carer or "consultee" who can give agreement for participation
- English language sufficient to be able to participate in an interview

INCLUSION CRITERIA Carers:

- Main informal carer or next of kin of a person diagnosed with dementia, of any sub type, during an acute hospital admission to Barts Health NHS Trust
- Have been informed of the diagnosis during the hospital admission
- Able to give written informed consent
- English language sufficient to be able to participate in an interview

It is not necessary for both the person with dementia and their carer to take part. If the person with dementia does not meet the inclusion criteria i.e. they haven't been told, they don't speak English – their carer can still take part, so long as they do meet the criteria i.e. they have been told, do speak English. If the carer does not want to take part but the person with dementia does this is also OK.

People will not be eligible to take part if:

EXCLUSION CRITERIA:

- People who have not been informed of their diagnosis
- People diagnosed with dementia who have no named carer or next of kin

If a person with dementia does not have a carer/ next of kin – they will not be able to take part. This is to safeguard the person with dementia as they will be being interviewed in their

own home by someone they have not met before, so it is important that someone close to them knows they are taking part (even if they are not taking part themselves).

2. When a patient and/or their carer meet the inclusion criteria you will use your own judgement as to the best time to approach them about the study.

- It might be best to take the study information with you when you go to see the person and/ or their carer and then decide at the time whether you think it is appropriate to introduce the study.
- When you introduce the study to the person with dementia and their carer you will give them a letter from me and an information sheet about the study.
- There are separate information leaflets for carers and people with dementia.
- There is a full version and an easy read version for people with dementia – you can give them both or one of these depending on their ability to read.
- It will be important for you to be positive and encouraging about taking part in the study – without coercing them!
- It will be helpful if you explain briefly what the study will entail e.g. being contacted by the researcher after they have been discharged, being interviewed by me at a venue of their choice.
- It may be reassuring for the carer/ next of kin to know that the person with dementia will not be contacted by me or interviewed without the carer/ next of kin arranging this. The only contact details passed on to me will be those of the carer/next of kin.

It is very important to stress that they do not need to make a decision at the time you approach them. Leave the information with them and say that they can let you know at any time before they are discharged if they want to be contacted by me.

- Before the person is discharged ask them if they would like to be contacted by me about the study – they still don't need to decide if they want to take part at this stage.
- You can offer them the opportunity to meet with me during their hospital admission to find out more about the study if they would rather do this than be contacted by someone they don't know after discharge.
- If they ask if the interviews could take place whilst they were still in hospital and this is their preference – I could arrange to do this, although please don't offer this as an option.
- Reassure the person that the only details you will pass on to me is the name and telephone number of the carer/next of kin. I will not have any of their other personal details or details of the person with dementia.

3. Contact details of the carer/ next of kin will be passed on to me

- With the agreement of the carer/ next of kin their name and telephone number will be passed on to me. If they would prefer to be contacted in another way e.g. email or by post, this is OK too.
- For data security purposes the contact details cannot be passed on via email/ voicemail. The best way to pass on the details will be to call me and give them to me personally over the phone. If I am not at my desk, leave a voicemail to say you have some contact details for me and I will call you back to get them.
- If the person is still in hospital when you pass on their details to me, I will call you back to check when they have been discharged.

Ethical concerns

- People with dementia won't want to take part in research
- What if the person lacks capacity to consent?
- The person with dementia is too unwell to take part
- The person has severe dementia – they won't be able to take part
- The carer is very stressed they won't want to take part
- What if the interview is distressing for the person with dementia?
- How do I know this study is appropriate for people with dementia?

Other Questions

How many people do we need to approach about the study?

Please approach as many people with dementia and their carers who meet the inclusion criteria as you can. Although my target sample is 5-6 people with dementia and 5-6 carers, my aim will be to interview probably twice as many in order to gain enough meaningful data for analysis e.g. 10-12 people with dementia, 10-12 carers. As not everyone you approach will agree to be contacted by me about the study my feeling is that around 50-60 people will need to be approached for me to interview around 10.

How will we know when to stop approaching people about the study?

I will let you know when you can stop approaching people about the study. I anticipate that recruitment will take 6 - 9months.

Will the DAD team be involved once the person has been discharged?

If during the course of my interviews the person with dementia and/or their carer asks for more support and wants to be referred to the Alzheimer's society or dementia care team in their local area, I will contact you and ask you to make the referral. I am not allowed to do this as I am undertaking the study in my role as a researcher and not as a clinician. I will leave pre-prepared information packs with the participants so they can contact these services themselves if they prefer.

Will the person's GP be informed?

The GP's will not be routinely informed. If after the interview I am asking you to make a referral to the ADS or DCT, I will let the person's GP know I have asked you to do this, with the person's consent.

What if a safeguarding concern is raised during the interviews?

I have made arrangements with the safeguarding team at BH to discuss any potential safeguarding concerns that arise with them. I may contact you after discussing with the safeguarding team if a referral to the DCT/ CMHT needs to be made.

Receiving a diagnosis of dementia during a hospital admission: exploring the perceptions of people with dementia and carers of people with dementia

Participant Information Sheet - Carer

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

There are a number of ways in which a person may come to receive a diagnosis of dementia. This study aims to find out your experiences and those of the person you care for, after receiving a diagnosis of dementia during an admission to hospital. This will help us to improve the information and services we provide.

We would like to find out

- What you thought about the memory problems of the person you care for before their admission to hospital
- What you think about their memory problems now
- How you decided whether to ask for help for their memory problems
- Whether you feel the diagnosis came at the right time for you and the person you care for

Michelle Parker (pictured below) is undertaking this study as part of a PhD degree at City University. The study will run from January 2017 to June 2020.

Why have I been invited?

You have been invited to take part because you have been identified as a carer of a person who recently received a diagnosis of dementia during an admission to hospital.

Do I have to take part?

No, taking part in this study is entirely voluntary. It is up to you to decide whether or not to take part. If you decide not to take part this will in no way affect the services you or the person you care for receives.

If you do decide to take part you will be asked to sign a consent form. If you decide to take part but then later change your mind, this is OK. You are free to withdraw at any time and without giving a reason.

What will happen if I take part?

We will contact you to arrange a time to come and see you at home or at a place convenient for you. We can answer any questions you have about the study and will show you how the interview will be recorded. We will check that you are happy for the interview to be audio - taped.

We would like to know about your experiences of caring for a person with memory problems before they were admitted to hospital. We will ask you what you thought about their memory problems and what other people might have said to you about their memory problems before their diagnosis. This is likely to take 1 – 1½ hours.

How many times will I be interviewed?

You will be interviewed once at the time most convenient to you. We may contact you to arrange to interview you again in 3-6 months' time to find out how things are going for you and the person you care for. We will ask what you think about their memory problems and whether anything has changed since they received their diagnosis.

Will I receive payment for taking part in the study?

No, we will visit you at home or at a place that is most convenient for you. This means you will not need to pay anything out of your pocket.

What do I have to do?

If you would like to receive more information about the study or would like to take part, a member of the liaison team will pass on your contact details to us. We will telephone you once your loved one has been discharged from hospital to arrange a time to come and see you.

What are the possible disadvantages and risks of taking part?

We think it is unlikely that you would come to any harm by taking part in this study. However, it is possible that asking you to talk about your experiences may be upsetting for you. The

guide for the interview is very open so you can choose which experiences you feel comfortable sharing.

What are the possible benefits of taking part?

There is no specific benefit to taking part in the study. However, you may enjoy knowing that you are contributing to the potential improvement of services in the future.

What will happen when the research study stops?

We will transcribe the recording of your interview onto a password protected computer. We will then analyse what people have said about their experiences.

The transcriptions of the interviews and audio recordings will be saved on a password protected computer for ten years after the study finishes. After this time the computer files will be destroyed.

Will my taking part in the study be kept confidential?

The recordings and transcriptions of the audio tapes will be kept on a password protected computer. Your name will not be on these transcriptions, only a code, so only we will know who took part in the interviews.

Michelle's academic supervisors may read some of the transcripts and her notes. But as these will be anonymous, they will not know they have come from you.

When we write up the results of the study or an article for publication about the study, a direct quote from your interview may be used. But this will be anonymous and no one will know that it has come from you.

There are some limits to confidentiality. If during your interview you tell Michelle something that makes her think you or someone else is at significant risk of harm, she will need to break confidentiality to discuss this with either her supervisors or experts that could help. Michelle will tell you if she feels she needs to do this and will discuss it with you.

What will happen to results of the research study?

The results of the study will be presented as part of Michelle's thesis for her PhD degree. We will also write about the research results for professional journals. We may present the results at academic conferences and conferences that link service

users with service providers and researchers like the Alzheimer's Society and National Dementia Congress.

We will also offer to talk to local service providers about the results.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. You do not need to tell us why you wish to stop the interviews. Withdrawing from the study will in no way affect the services you receive.

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you

can do this through the University complaints procedure. To complain about the study, you need to phone [redacted]. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is: Receiving a diagnosis of dementia during a hospital admission: exploring the perceptions of people with dementia and their carers.

You could also write to the Secretary at:

[redacted]
Secretary to Senate Research Ethics Committee

Research Office, E214
City University London
Northampton Square
London
EC1V 0HB

Email: [redacted]

City University London holds insurance policies which apply to this study. If you feel you have been harmed or injured by taking part in this study you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Who has reviewed the study?

This study has been approved by the National Research Ethics Service.

Further information and contact details

If you have any questions about the study you can contact Michelle Parker [redacted]

[redacted]

Thank you for taking the time to read this information leaflet

Additional information about General Data Protection Regulations (GDPR)

City, University of London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. City, University of London will keep identifiable information about you for up to 3 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information https://www.city.ac.uk/about/governance/legal

City, University of London will use your name and contact details to contact you about the research study and make sure relevant information about the study is recorded and to oversee the quality of the study. Individuals from City, University of London and regulatory organisations may look at your research records to check the accuracy of the research study. North Middlesex NHS Trust will pass your contact details to City, University of London. The only people in City, University of London who will have access to information that identifies you will be the researcher who needs to contact you to arrange an interview. No other researchers will be able to identify you and or be able to find out your name or contact details.

Receiving a diagnosis of dementia during a hospital admission: exploring the perceptions of people with dementia and carers of people with dementia

Participant Information Sheet - Carer

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

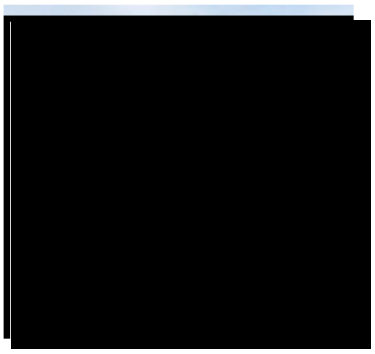
What is the purpose of the study?

There are a number of ways in which a person may come to receive a diagnosis of dementia. This study aims to find out your experiences and those of the person you care for, after receiving a diagnosis of dementia during an admission to hospital. This will help us to improve the information and services we provide.

We would like to find out

- What you thought about the memory problems of the person you care for before their admission to hospital
- What you think about their memory problems now
- How you decided whether to ask for help for their memory problems
- Whether you feel the diagnosis came at the right time for you and the person you care for

Michelle Parker (pictured below) is undertaking this study as part of a PhD degree at City University. The study will run from January 2017 to June 2020.



Why have I been invited?

You have been invited to take part because you have been identified as a carer of a person who recently received a diagnosis of dementia during an admission to hospital.

Do I have to take part?

No, taking part in this study is entirely voluntary. It is up to you to decide whether or not to take part. If you decide not to take part this will in no way affect the services you or the person you care for receives.

If you do decide to take part you will be asked to sign a consent form. If you decide to take part but then later change your mind, this is OK. You are free to withdraw at any time and without giving a reason.

What will happen if I take part?

We will contact you to arrange a time to come and see you at home or at a place convenient for you. We can answer any questions you have about the study and will show you how the interview will be recorded. We will check that you are happy for the interview to be audio - taped.

We would like to know about your experiences of caring for a person with memory problems before they were admitted to hospital. We will ask you what you thought about their memory problems and what other people might have said to you about their memory problems before their diagnosis. This is likely to take 1 – 1½ hours.

How many times will I be interviewed?

You will be interviewed once at the time most convenient to you. We may contact you to arrange to interview you again in 3-6 months' time to find out how things are going for you and the person you care for. We will ask what you think about their memory problems and whether anything has changed since they received their diagnosis.

Will I receive payment for taking part in the study?

No, we will visit you at home or at a place that is most convenient for you. This means you will not need to pay anything out of your pocket.

What do I have to do?

If you would like to receive more information about the study or would like to take part please contact Michelle via the details at the end of the information sheet. We will then telephone you to arrange a time to come and see you.

What are the possible disadvantages and risks of taking part?

We think it is unlikely that you would come to any harm by taking part in this study. However, it is possible that asking you to talk about your experiences may be upsetting for you. The guide for the interview is very open so you can choose which experiences you feel comfortable sharing.

What are the possible benefits of taking part?

There is no specific benefit to taking part in the study. However, you may enjoy knowing that you are contributing to the potential improvement of services in the future.

What will happen when the research study stops?

We will transcribe the recording of your interview onto a password protected computer. We will then analyse what people have said about their experiences.

The transcriptions of the interviews and audio recordings will be saved on a password protected computer for ten years after the study finishes. After this time the computer files will be destroyed.

Will my taking part in the study be kept confidential?

The recordings and transcriptions of the audio tapes will be kept on a password protected computer. Your name will not be on these transcriptions, only a code, so only we will know who took part in the interviews.

Michelle's academic supervisors may read some of the transcripts and her notes. But as these will be anonymous, they will not know they have come from you.

When we write up the results of the study or an article for publication about the study, a direct quote from your interview may be used. But this will be anonymous and no one will know that it has come from you.

There are some limits to confidentiality. If during your interview you tell Michelle something that makes her think you or someone else is at significant risk of harm, she will need to break

confidentiality to discuss this with either her supervisors or experts that could help. Michelle will tell you if she feels she needs to do this and will discuss it with you.

What will happen to results of the research study?

The results of the study will be presented as part of Michelle's thesis for her PhD degree. We will also write about the research results for professional journals. We may present the results at academic conferences and conferences that link service users with service providers and researchers like the Alzheimer's Society and National Dementia Congress.

We will also offer to talk to local service providers about the results.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. You do not need to tell us why you wish to stop the interviews. Withdrawing from the study will in no way affect the services you receive.

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you can do this through the University complaints procedure. To complain about the study, you need to phone [redacted] You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is: Receiving a diagnosis of dementia during a hospital admission: exploring the perceptions of people with dementia and their carers.

You could also write to the Secretary at:

[redacted]
Secretary to Senate Research Ethics Committee

Research Office, E214
City University London
Northampton Square
London
EC1V 0HB

[redacted]

City University London holds insurance policies which apply to this study. If you feel you have been harmed or injured by taking part in this study you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Who has reviewed the study?

This study has been approved by the National Research Ethics Service.

Further information and contact details

If you have any questions about the study you can contact Michelle Parker [redacted]

Thank you for taking the time to read this information leaflet

Additional information about General Data Protection Regulations (GDPR)

City, University of London is the sponsor for this study based in the United Kingdom. We will be using information from you in

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Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information https://www.city.ac.uk/about/governance/legal

City, University of London will use your name and contact details to contact you about the research study and make sure relevant information about the study is recorded and to oversee the quality of the study. Individuals from City, University of London and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in City, University of London who will have access to information that identifies you will be the researcher who needs to contact you to arrange an interview. No other researchers will be able to identify you and or be able to find out your name or contact details.

Receiving a diagnosis of dementia during a hospital admission: exploring the perceptions of people with dementia and carers of people with dementia

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide whether you would like to take part it is important that you understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

There are a number of ways in which a person may come to receive a diagnosis of dementia. This study aims to find out how you felt about receiving a diagnosis of dementia during an admission to hospital. This will help us to improve the information and services we provide.

We would like to find out

- What you thought about your memory problems before your admission to hospital
- What you think about your memory problems now
- How you decided whether to ask for help for your memory problems
- Whether you feel the diagnosis came at the right time for you

Michelle Parker (pictured below) is undertaking this study as part of a PhD degree at City University. The study will run from January 2017 to June 2020.

Why have I been invited?

You have been invited to take part because you have recently received a diagnosis of dementia during an admission to hospital.

Do I have to take part?

No, taking part in this study is entirely voluntary. It is up to you to decide whether or not to take part. If you decide not to take part this will in no way affect the services you receive.

If you do decide to take part you will be asked to sign a consent form. If you decide to take part but then later change your mind, this is OK. You are free to withdraw at any time and without giving a reason.

What will happen if I take part?

We will contact you and your carer to arrange a time to come and see you at home or at a place convenient for you. We can answer any questions you have about the study and will show you how the interview will be recorded. We will check that you are happy for the interview to be audio - taped.

We would like to know about your experiences of having memory problems before you were admitted to hospital. We will ask you what you thought about your memory problems and

what other people might have said to you about your memory problems before your diagnosis. This is likely to take 30mins – 1 hour.

How many times will I be interviewed?

You will be interviewed once at the time most convenient to you. We may contact you and your carer to arrange to see you again in 3-6 months' time to find out how things are going for you. We will ask what you think about your memory problems and whether anything has changed since you received your diagnosis. This is likely to take 30mins- 1 hour.

Will I receive payment for taking part in the study?

No, we will visit you at home or at a place that is most convenient for you. This means you will not need to pay anything out of your pocket.

What do I have to do?

If you would like to receive more information about the study or would like to take part, a member of the liaison team will pass on the contact details of your carer to us. We will telephone them once you have been discharged from hospital to arrange a time to come and visit you.

What are the possible disadvantages and risks of taking part?

We think it is unlikely that you would come to any harm by taking part in this study. However, it is possible that asking you to talk about your experiences may be upsetting for you. The guide for the interview is very open so you can choose which experiences you feel comfortable sharing.

What are the possible benefits of taking part?

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What will happen when the research study stops?

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Michelle's academic supervisors may read some of the transcripts and her notes. But as these will be anonymous, they will not know they have come from you.

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There are some limits to confidentiality. If during your interview you tell Michelle something that makes her think you or someone else is at significant risk of harm, she will need to break confidentiality to discuss this with either her supervisors or experts that could help. Michelle will tell you if she feels she needs to do this and will discuss it with you.

What will happen to results of the research study?

The results of the study will be presented as part of Michelle's thesis for her PhD degree. We will also write about the research results for professional journals. We may present the results at academic conferences and conferences that link service users with service providers and researchers like the Alzheimer's Society and National Dementia Congress.

We will also offer to talk to local service providers about the results.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. You do not need to tell us why you wish to stop the interviews. Withdrawing from the study will in no way affect the services you receive.

What if there is a problem?

If you have any problems, concerns or questions about this study, you should ask to speak to a member of the research team. If you remain unhappy and wish to complain formally, you can do this through the University complaints procedure. To complain about the study, you need to phone [redacted]. You can then ask to speak to the Secretary to Senate Research Ethics Committee and inform them that the name of the project is: Receiving a diagnosis of dementia during a hospital admission:

exploring the perceptions of people with dementia and their carers.

You could also write to the Secretary at:

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City University London holds insurance policies which apply to this study. If you feel you have been harmed or injured by taking part in this study you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

Who has reviewed the study?

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Further information and contact details

If you have any questions about the study you can contact Michelle Parker [redacted]

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Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information https://www.city.ac.uk/about/governance/legal

City, University of London will use your name and contact details to contact you about the research study and make sure relevant information about the study is recorded and to oversee the quality of the study. Individuals from City, University of London and regulatory organisations may look at your research records to check the accuracy of the research study. North Middlesex NHS Trust will pass your contact details to City, University of London. The only people in City, University of London who will have access to information that identifies you will be the researcher who needs to contact you to arrange an interview. No other researchers will be able to identify you or be able to find out your name or contact details.

Receiving a diagnosis of dementia during a hospital admission

You are being invited to take part in a research project. Research projects help us to find out new things.

This project is for people with dementia. It is about your experiences – how you feel and why.

What am I being asked to do?

You will be interviewed in your own home or wherever you feel most at ease. A family member or friend can stay with you if you want them to.

Your comments will be recorded and every word and phrase from the interviews in the project will be looked at to see what the common ideas are.

Talking about how you feel may be upsetting. But you only have to talk about experiences you feel comfortable with.

You might enjoy the interview and you could be helping us to improve services for people with dementia in the future.

Do I have to take part?

It is up to you if you take part or not. Feel free to talk to your family and friends, if this helps you to decide.

If you decide you don't want to take part – that is OK.

If you do want to take part you will be asked to sign a consent form. This is to say that you have understood what the project involves and you are happy to take part.

You can choose to leave the project at any time. You do not have to give a reason.

What will happen after the interview?

The recordings and notes from the interview will be kept safe. They will not have your name on them. Only the researcher will know exactly what you have said.

The Health Research Authority makes sure all health research in England is safe. They have agreed that this project is safe.

Thank you for taking the time to read this leaflet

Appendix 12 Phase 2 - Interview Topic Guide

Tell me about when you first noticed there was something wrong with your (relative)'s memory

Possible prompts/ follow on questions:

- How did this make you feel?
- What did you think was causing the problems?
- Did you do anything to help them or you manage the problems?
- Did you talk to your relative about their problem – why not?
- Did you talk to anyone else – why/ why not?
- Did you think about seeking help from anyone else (e.g. GP/ nurse) – why/ why not/ what stopped you?

Can you tell me about how the diagnosis of dementia in hospital came about?

Possible prompts/ follow on questions:

- Who mentioned memory problems to the doctors?
- Who spoke to you about it?
- How did this make you feel?

Now that you know the cause of your (relative)'s memory problems, how do you feel?

Do you feel like anything has changed as a result of your (relative)'s dementia diagnosis?

Possible prompts/ follow on questions:

- In terms of practical changes, social support?
- In terms of how you think they feel? Their relationships with others? Can you give me an example…?
- In terms of your relationship with them? Can you give me an example…?

Do you feel receiving the diagnosis whilst they were in hospital came at the right time for you?

Possible prompts/ follow on questions:

- Why/ why not?
- When would have been the right time?
- What do you think would have happened if they hadn't received a diagnosis whilst they were in hospital?

Appendix 13 Phase 2 - Consent Form

Receiving a diagnosis of dementia during a hospital admission: exploring the perceptions of people with dementia and carers of people with dementia

Consent form

1.	I agree to take part in the above City University London research project. I have had the project explained to me, and I have read the participant information sheet, which I may keep for my records. I understand this will involve • being interviewed by the researcher • allowing the interview to be audiotaped • being approached to take part in a further interview in 3 to 6 months' time	
2.	This information will be held and processed for the following purposes: The researcher's PhD study and any subsequent publication or presentation I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party. No identifiable personal data will be published. The identifiable data will not be shared with any other organisation. I understand that I will be given the opportunity to see a transcript of the interview if I wish, before it is included in the write-up of the research. I understand that confidentiality cannot be guaranteed for certain types of information which I might disclose in the interviews.	

3.	I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw at any stage of the project without being penalized or disadvantaged in any way.	
4.	I agree to City University London recording and processing this information about me. I understand that this information will be used only for the purpose(s) set out in this statement and my consent is conditional on the University complying with its duties and obligations under the Data Protection Act 1998.	
5.	I agree to take part in the above study.	

_____	_____	_____
Name of Participant	Signature	Date
_____	_____	_____
Name of Researcher	Signature	Date

When completed, 1 copy for participant; 1 copy for researcher file.

Appendix 14 Phase 3 - STROBE Criteria for reporting cohort studies

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	P200
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	P200
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	P201
Objectives	3	State specific objectives, including any prespecified hypotheses	P95/202
Methods			
Study design	4	Present key elements of study design early in the paper	P95-100 /202-203
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	P96-97/202
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	P97-98/202
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	P98-99/ 202 / App 15
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	P98-99/ 202-203
Bias	9	Describe any efforts to address potential sources of bias	P99
Study size	10	Explain how the study size was arrived at	P98/203
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	P100/ 203

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	P100/ 203
		(*b*) Describe any methods used to examine subgroups and interactions	P100/ 203
		(*c*) Explain how missing data were addressed	N/A
		(*d*) If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	P203
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	P204
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	P204-207
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	P204-211
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	P204-211
Discussion			
Key results	18	Summarise key results with reference to study objectives	P204-211
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	P215

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	P212-215
Generalisability	21	Discuss the generalisability (external validity) of the study results	P215
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for exposed and unexposed groups

Appendix 15 Data categories and codes

Variable	Variable name	Coding Instructions
Identification number	ID	Number assigned to each patient
Referral source	Ref source	1= GP 2= Hospital 3= other
Gender	Sex	1= female 2= male
Age	Age	Age in years
Ethnic Group (ONS groupings)	Ethnicity	1= White (English/Welsh/Scottish/Northern Irish/Irish/ British/Gypsy or Irish traveller/other white background) 2= Asian/Asian British (Indian, Pakistani, Bangladeshi, Chinese, other Asian) 3= Black/African/Caribbean/Black British 4= Mixed/multiple ethnic group 5=other not stated
Diagnostic outcome	Outcome	1= Diagnosis Alzheimer's disease 2= Diagnosis Vascular Dementia 3= Diagnosis Mixed AD and VaD 4= Diagnosis other Dementia 5= Diagnosis mild cognitve impairment/ vascular cognitive impairment 6= other non Dementia diagnosis 7= diagnosis cognitvely intact 8= did not attend appointment/ refused assessment 9= unable to assess due to died before assessment/ not appropriate due to terminal illness/ moved out of area/unable to make contact
Severity of dementia at time of diagnosis	Severity	1= not applicable as no dementia diagnosis 2= mild 3= mild to moderate 4 = moderate 5= moderate to severe 6= severe 7= not confirmed
Number of hospital admissions in the 12 months prior to referral to memory clinic	Hosp Adm pre	1 = 0 admissions 2 = 1 admission 3 = 2 admissions 4 = 3 admissions 5 = 4 or more admissions
Number of hospital admissions in the 12 months post referral to memory clinic	Hosp Adm post	1 = 0 admissions 2 = 1 admission 3 = 2 admissions 4 = 3 admissions 5 = 4 or more admissions

Mortality at six months post referral	Mort 6	1= alive at 6 months 2 = dead at 6 months
Mortality at twelve months post referral	Mort 12	1= alive at 6 months 2 = dead at 6 months

Appendix 16 Health Research Authority UK Policy Framework for Health and Social Care Research

Principle 1: Safety – the safety and well-being of the individual prevail over the interests of science and society
Principle 2: Competence – all the people involved in managing and conducting a research project are qualified by education, training and experience or otherwise competent under the supervision of a suitably qualified person, to perform their tasks
Principle 3: Scientific and Ethical Conduct - Research projects are scientifically sound and guided by ethical principles in all their aspects.
Principle 4: Patient, Service User and Public Involvement - Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.
Principle 5: Integrity, Quality and Transparency - Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.
Principle 6: Protocol - The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents
Principle 7: Legality - The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research
Principle 8: Benefits and Risks - Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated
Principle 9: Approval - A research project is started only if a research ethics committee and any other relevant approval body have favourably reviewed the research proposal or protocol and related information, where their review is expected or required
Principle 10: Information about the Research - In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee)
Principle 11: Accessible Findings - Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance

with any applicable regulatory standards, i.e. legal requirements or expectations of regulators. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.
Principle 12: Choice - Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.
Principle 13: Insurance and Indemnity - Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.
Principle 14: Respect for Privacy - All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected33 . Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.
Principle 15: Compliance - Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

Study Protocol

The timeliness of receiving a dementia diagnosis during an acute hospital admission: exploring the perceptions of people with dementia and carers of people with dementia.

Short study title:

Receiving a dementia diagnosis during a hospital admission

PROTOCOL VERSION NUMBER AND DATE

Version 1.0 05/10/2016

This protocol has regard for the HRA guidance and order of content

RESEARCH REFERENCE NUMBERS

IRAS Number:	208826
SPONSORS Number:	PhD/16-17/03

SIGNATURE PAGE

The persons named below confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Dr. Mark Haddad Date: 4/10/16

Position:

Senior Tutor for Research, School of Health Sciences

Chief Investigator:

Michelle Parker Date: 5/10/16

KEY STUDY CONTACTS

Chief Investigator	Michelle Parker, School of Health Sciences, City, University of London, [redacted]
Academic supervisor	Professor Julienne Meyer, School of Health Sciences, City, University of London [redacted]
Study Co-ordinator	Michelle Parker (as above)
Sponsor	City, University of London, School of Health Sciences Sponsor contact: Alison Welton Research Governance Officer Research Office Northampton Square London EC1V 0HB [redacted]

Study Title	The timeliness of receiving a dementia diagnosis during an acute hospital admission: exploring the perceptions of people with dementia and carers of people with dementia.
Internal ref. no. (or short title)	Receiving a dementia diagnosis during a hospital admission
Study Design	Qualitative study using Interpretative Phenomenological Analysis
Study Participants	People with dementia diagnosed during an acute hospital admission and carers of people with dementia diagnosed during an acute hospital admission
Planned Size of Sample (if applicable)	5-6 people with dementia, 5-6 carers
Follow up duration (if applicable)	3 – 6 months
Planned Study Period	January 2017 – December 2017
Research Question/Aim(s)	To explore whether receiving a diagnosis of dementia during a hospital admission, when you have not sought help previously, comes at the right time for the person diagnosed and carers of those diagnosed

STUDY SUMMARY

In the UK there are around 800,000 people living with dementia. However only around two thirds of people ever receive a formal diagnosis. Research has shown that there are a number of reasons why people don't seek help for signs of dementia, including thinking that memory problems are part of normal ageing and that there is nothing that can be done to help.

Receiving an early diagnosis of dementia – that is, early in the disease process before symptoms progress - is often thought to be important. But there are pros and cons to receiving an early diagnosis. Increasingly it is recognised that we should be aiming to provide a timely diagnosis – that is, at the right time for the person. However there is little agreement as to what "timely" really means and how people with symptoms of dementia and their families or carers decide when the "right time" is to seek a diagnosis.

Health care professionals in acute hospitals have been encouraged over the last few years to identify people who may have signs and symptoms of dementia when they are admitted to hospital for other physical problems. This can sometimes result in the person being given a diagnosis of dementia during their hospital admission. As these people have not usually sought help for their signs of dementia before being admitted to hospital, we do not know if receiving a diagnosis of dementia during their hospital admission comes at the right time for them.

This study aims to explore the timeliness and meaning of receiving a dementia diagnosis during an acute hospital admission, from the perspective of people with dementia and from the perspective of families/ carers of people with dementia. To achieve this I aim to interview 5-6 people who have been diagnosed with dementia during an acute hospital admission and 5-6 carers of people who have been diagnosed during a hospital admission. They will each be interviewed twice. The first interview will take place in the few weeks after they have been discharged from hospital. This will be to explore whether they think the diagnosis has come at the right time for them and their reasons for not seeking help prior to their hospital admission. The second interview will take place 3-6 months later and will aim to explore if their thoughts about the diagnosis have changed and whether they would consider it to be timely or not.

The results of this study will help us to understand the process people go through when deciding whether or not to seek help for signs of dementia and whether receiving a diagnosis when you are not seeking help could be considered timely. This could help us in future to support people to access help that leads to a diagnosis at the right time for them. This may mean improving access to services so that people can seek help earlier in the disease process or by providing alternative support for the person until they are ready to be assessed and receive a diagnosis.

FUNDING

This is an unfunded PhD study. No external funding has been obtained for this research.

ROLE OF STUDY SPONSOR

The sponsor for this unfunded PhD study is City, University of London, School of Health Sciences. The sponsor is the main employer of the chief investigator and the academic institution that the chief investigator is registered to study with.

It is the role of the sponsor to ensure that adequate insurance and indemnity arrangements are in place for the study and these are detailed in section 8.9. As this study forms part of the chief investigators PhD, it is the responsibility of the sponsor to ensure that the chief investigator is properly supported and supervised. The chief investigator's primary supervisor is a Professor within the School of Health Sciences who is internationally recognized for her research involving the care of older people. Her second supervisor is a visiting Professor in the School of Health Sciences who is nationally recognized for his research and work involving older people and works as a consultant geriatrician within the NHS.

The chief investigator receives monthly supervision from her academic supervisors and they have reviewed the study protocol, study design and methodology, the scale of the research and potential for harm to participants to ensure the chief investigator is appropriately prepared to undertake this study.

As a condition of the sponsorship for this study, the School may audit compliance with the School Research Governance Framework at any time.

Protocol contributors

As described above the study sponsor will be involved in the study design, conduct, data analysis and interpretation in the form of academic supervision for the chief investigator's PhD. People with dementia and their carers attending the Waltham Forest Alzheimer's Society dementia cafe have contributed to a review of the study design, design of the participant information sheets and interview schedules.

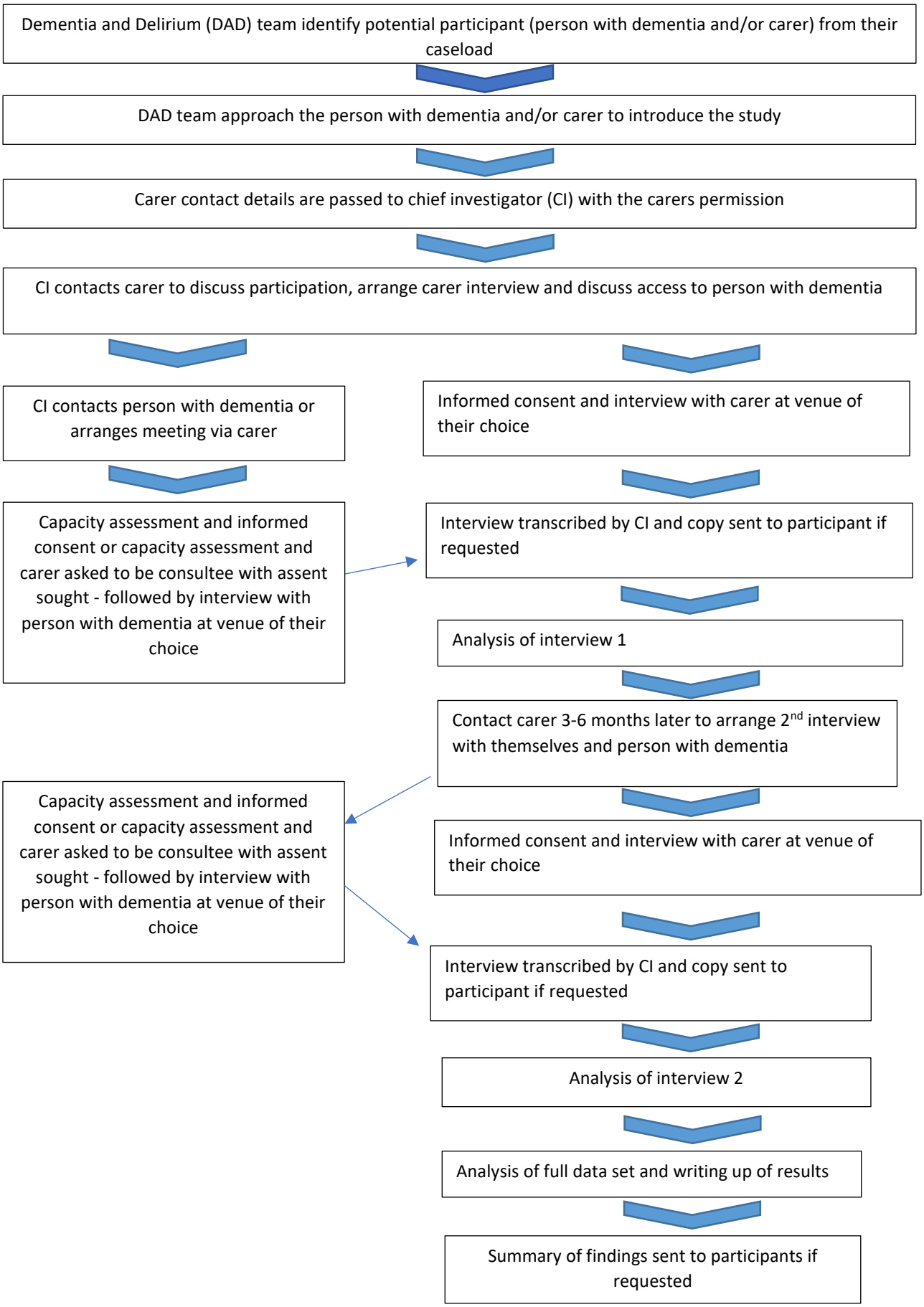
This protocol was written by the chief investigator but has been reviewed by her academic supervisors and notable experts in the field of dementia research and Interpretative Phenomenological Analysis, as outlined in section 8.4.

There are no conflicts of interest to declare.

KEY WORDS: Dementia diagnosis, timely diagnosis, interpretative phenomenological analysis, in depth interviews, people with dementia, carers

LIST of CONTENTS

Study Flow Chart



STUDY PROTOCOL

The timeliness of receiving a dementia diagnosis during an acute hospital admission: exploring the perceptions of people with dementia and carers of people with dementia.

1. BACKGROUND

Dementia is a progressive illness that currently has no cure. It is estimated that around 800,000 people in the UK have dementia (Parkin & Baker 2015), although the number of people who have received a formal diagnosis is thought to be considerably less.

In 2010/11 it was reported that less than half of those estimated to have dementia (42%) had received a formal diagnosis (Parkin & Baker 2015). Subsequently NHS England introduced incentives in both primary and secondary care to improve identification and referral of those people suspected to have dementia and Health Education England set targets to increase the number of health care professionals receiving dementia awareness training (Parkin & Baker 2015). In addition to this the UK's leading dementia support and research charity – The Alzheimer's Society, have run media and education campaigns to raise awareness of dementia amongst the general public.

As a result, in March 2016, the diagnosis rate was reported to have increased to 67% (Parkin & Baker, 2015, updated March 2016). However it is difficult to say how much of the increase is due to increased public awareness of the signs and symptoms of dementia. Tullman et al (2007), in discussing why mass media campaigns to improve awareness of symptoms of acute myocardial infarction had not worked, suggested that focusing on increasing knowledge and awareness does not address the complex cognitive, emotional and social factors that play a part in the delay to help seeking. This could explain why there remains a significant proportion of people with dementia without a formal diagnosis.

One of the key arguments for improving dementia diagnosis rates has been the proposed benefits to the person with dementia and their carers of having a diagnosis made early in the disease process. Early diagnosis has been advocated for in dementia strategies and policy worldwide. Yet despite there being strong arguments in favour of early diagnosis, for example the ability to plan for the future and access services (Dementia Action Alliance 2013), prescription of medication which may slow progression of the disease and education for carers and those with dementia about what to expect (Leifer 2003), these are not always supported by research evidence (Prince et al 2011). A number of authors have stressed the harm an early diagnosis may bring to the person with dementia and their families for example anxiety and depression, stigmatization and isolation, a change in role and relationships and a loss of self-esteem (Bunn et al 2012, Dementia Action Alliance 2013).

Increasingly the term "timely diagnosis" is being used in preference to "early diagnosis". The concept of a "timely diagnosis", that is "at the right time for the person" seems appropriate. But there is little consensus in the literature of what "timely" really means and how we would know when the right time for the person and their carer is. In fact the terms "early" and "timely" are often used interchangeably within policy and literature.

Many studies have attempted to determine the barriers to help seeking for dementia diagnosis and care. Werner (2014) in a systematic review of help seeking for dementia concluded that there were three main barriers: *socioeconomic barriers* including low education, being a

minority and low income; *beliefs* including that cognitive impairment is part of normal aging, that there is nothing that can be done and that it is the family's responsibility to care for family members; and *knowledge and experience* including inadequate knowledge of dementia and previously bad experiences with health care services.

However a number of qualitative studies have explored the perspectives of people with dementia (Keady & Nolan 1995, Robinson et al 1997) and their carers (Wilson 1989, Keady & Nolan 1994, van Vilet et al 2011) at different stages in the dementia disease process and describe a number of stages they both go through before they seek help and a diagnosis. They all describe a process of gradual realisation that something is wrong, both from the carer and person with dementia's perspective, which culminates in seeking help outside of the family, sometimes years later, when the person has significant cognitive impairments. The stages leading to the point of help seeking are not described as a time of delay in these studies by either the carer or the person with dementia but appear to be an important part of a process in understanding what is happening to them and what this might mean for the future.

The findings of a recent synthesis of nine studies (Perry-Young et al, 2016) looking at how people experience and interpret the early signs of dementia and decide to seek help also concluded that recognition and help seeking were part of a long process. They concluded that interpersonal factors, including familial and cultural factors, were important in the way people make help seeking decisions but that these concepts were underdeveloped in existing studies. They recommend that further research is needed to explore the complexities involved in the interpersonal aspects of decision making.

This study aims to further our understanding of the time before a diagnosis of dementia, focusing specifically on these interpersonal factors and the influence they have on deciding when the right time is to seek help. This qualitative study will use Interpretative phenomenological analysis to understand the meaning and experience of receiving a dementia diagnosis during an acute hospital admission, when you haven't sought help for memory problems previously.

In contrast to previous studies, this study will involve interviewing people who had not yet reached the point of seeking help for a diagnosis when they were admitted to hospital. By exploring the perceptions of this group of people with dementia and their carers we can begin to understand whether the diagnosis was "timely" for them and how people decide when the "right time" is. In doing so we can start to understand what a timely diagnosis is and how we can support people to access help that leads to a diagnosis at the right time for them. This may mean improving access to services so that people can seek help earlier in the process or it may mean providing alternative support until the person is ready to be assessed and receive a diagnosis. It is possible that the "right time" may be different for the person receiving the diagnosis and carers of people receiving a diagnosis. Consequently this study aims to interview both the person diagnosed with dementia and carers to determine whether there are differences in the meaning and timeliness of the diagnosis for each of them.

This study is an educational project and will fulfill part of the chief investigator's PhD at City, University of London. The chief investigator is a lecturer in adult nursing at City but until recently worked as a Consultant Nurse for older people and dementia in the NHS. A large part of this clinical role involved assessing people admitted to hospital who were suspected of

having dementia, but had not sought help previously. Following assessment and consultation with the person with symptoms and their family/ carers, the chief investigator would feedback a care plan and/or diagnosis of dementia to the person and their family, as part of a multidisciplinary liaison service. The considerable demographic variation in the patients assessed and diagnosed as part of this service led the chief investigator to question the process that takes place before the person is admitted to hospital and the reasons why some people seek help early in the disease process and others do not. The additional health problems this group of patients commonly had often took precedence, in both the minds of the person with dementia and their carers, leading the chief investigator to question the timeliness of the dementia diagnosis. Following a review of the literature surrounding help seeking for diagnosis, there is already a body of literature examining the barriers to help seeking, as described above, but the complex process of determining when the right time to seek help is and the factors that influence this is under-researched. To the knowledge of the chief investigator, no one has explored the perspectives of a group of people diagnosed with dementia during an acute hospital admission, who had not sought help previously. Hence this study will add to the body of knowledge around why people do not seek help and begin to help us understand the perspectives of this unique group of people with dementia and their carers who happen upon a diagnosis of dementia whilst being treated for an acute medical or surgical problem.

2. RATIONALE

People with dementia often do not seek help when they first notice problems with their memory and this can result in a formal diagnosis of dementia being made late in the disease process. There is much focus on encouraging early diagnosis of dementia at present and acute hospitals have been encouraged to identify patients who may be showing signs of dementia. It is recognised that making a dementia diagnosis during an acute hospital admission is not an ideal situation. Both delirium secondary to acute medical/ surgical problems and the unfamiliar, stressful setting of a hospital environment are likely to mean that cognitive assessments underestimate a person's cognitive abilities. But for some people it may be appropriate. However we do not know if receiving a diagnosis of dementia during an acute hospital admission for an unrelated problem comes at the right time for the person diagnosed with dementia or the carer of a person diagnosed. The questions this study aims to explore are:

1. How do people perceive the timeliness of a diagnosis of dementia made during an acute hospital admission and does this change over time?
2. How do people perceive their memory problem (or that of the person they care for) prior to hospitalization and does this influence their help seeking decision making process?
3. What are the factors that influence the subsequent decision not to seek professional help?
4. Are there differences between people with dementia and carers in the timeliness and meaning of the diagnosis and perspectives on help seeking?

5. Does this group of people diagnosed with dementia and carers of those diagnosed differ, in regards to their help seeking decision making process and the meaning of the diagnosis, to those who do seek help as reported in the literature?

In the wake of the introduction of case finding incentive schemes to identify people with suspected dementia in primary care, there ensued a debate in the UK medical press about the difference between "early" and "timely" diagnosis (see Brunet et al 2012). This resulted in the acknowledgment that the terminology around dementia diagnosis was important and that "timely" should be used in place of "early" diagnosis (Burns and Buckman, 2013). Yet in literature and policy on dementia diagnosis, some documents continue to advocate for an early diagnosis, whilst others argue for a timely diagnosis and in some cases for both (Burns 2012). But more often than not, the terms are used synonymously and taken to mean a diagnosis made in the early stages of the disease process. Where definitions of a "timely diagnosis" are given, the person with dementia and their carer are central to initiating the diagnostic process (Prince et al 2011, Cuijpers and van Lente 2014, British Psychological Society quoted in Dementia Action Alliance 2013). There is also a strong emphasis on "timing" and the sense that this determined by the person with dementia. Dhedi et al (2014) in their narrative study of GP perspectives on the meaning of timeliness in dementia diagnosis, found that GP's saw themselves as "fellow travelers" in the journey towards a diagnosis with their patients, weighing up the unique factors of each individual and stressed that the consequentiality of the diagnosis trumped the urgency of the diagnosis. Yet to date there are no studies exploring the concept of timeliness from the perspective of the person with dementia or carer of the person with dementia. If we are to continue advocating for a timely diagnosis of dementia, then understanding what this means to people being diagnosed and their carers and understanding how they come to decide when the right time is, will be essential.

The James Lind Alliance in their Dementia priority setting partnership (Kelly et al 2015) identified a top ten list of known uncertainties in dementia diagnosis, care and treatment that warranted further research, in addition to a long list of further known uncertainties. A number of these concerned diagnosis and included: How can primary care support a more effective route to diagnosis including the best way to communicate a diagnosis and where diagnosis should be delivered, the psychological impact of a diagnosis on persons and their carers; does a frail older person with multiple comorbidities benefit from having a diagnosis of dementia and how can GP's be made more aware of the concerns of people and carers regarding a possible diagnosis of dementia. Whilst this study does not directly answer these questions, it is likely that data generated by this study could begin to inform some of these uncertainties around diagnosis and help to generate avenues for further research. For example understanding why the group of people in this study did not seek help from primary care, whether they felt a diagnosis being delivered in hospital was appropriate, the impact the diagnosis has had and whether multiple co-morbidities are a factor in the help seeking decision making process.

As part of the chief investigator's PhD there is also an educational rationale for undertaking this study. In doing so the chief investigator aims to develop their own research skills and knowledge, in addition to adding to the body of knowledge in this important area of work.

3. THEORETICAL FRAMEWORK

Interpretative Phenomenological Analysis (IPA) has been chosen as the philosophical and methodological basis for this study. It is an approach that is suited to health research exploring experiences of a particular illness or health care experience (Malson, 2010). It is an approach to qualitative research that draws on three areas of philosophy – phenomenology, hermeneutics and idiography. Developed by Smith in 1996, IPA is concerned with how people make sense of major life experiences (Smith et al 2009). Phenomenology is concerned with understanding the lived experience of individuals and IPA theorizes that an experience can be understood by examining the meanings placed upon it by an individual (Smith et al 2009). Hermeneutics is the theory of interpretation and IPA is always interpretative (Smith et al 2009). It involves both trying to understand what an experience is like for an individual and then on a number of levels of analysis, interpreting what the experience means. Finally idiography is concerned with the particular and in the case of IPA this means that rather than make claims at a group or population level, it is committed to detail and understanding how a particular experience has meaning for particular people. To gain this deeper understanding of how individual's make sense of their experience and subsequently to analyse the nuances within and between individual accounts, small purposively selected samples or single case studies are advocated (Smith et al 2009).

In choosing an appropriate methodology to conduct research involving people with dementia, both the presence and impact of cognitive impairment needs to be considered (Clare, 2003). Clare who has used IPA in a number of studies involving people with dementia and their carers (2003, Clare et al 2008, Quinn et al 2008) describes the use of IPA as "an entirely feasible method" (2003, p1026), which allows the researcher to explore the perspectives of the person with dementia and then relate these to information gained from other sources and to other perspectives. In contrast to other qualitative approaches she states that IPA is an approach which attempts "to understand what participants believe and think about the topic in question, assuming some form of link between self-report and underlying cognition" (Clare 2003, p1019).

IPA is an appropriate choice as this study aims to understand the meaning of receiving a diagnosis of dementia during a hospital admission in order to determine whether this was at the right time for the individual and their carer. The way people perceive their own health problems (or those of the people they care for) and subsequently to decide whether or not to seek help is outside the realm of our understanding (Biggerstaff and Thompson, 2008), unless we specifically seek to understand it. IPA offers an approach through which participants can talk freely about their experiences and with prompting and probes from the interviewer, the meaning of their memory problems, their help seeking decision making process and their diagnosis experience can be explored. The aim is not to be able to generalise findings to a wider population but to be able to provide a rich and transparent account, rooted in the words of participants, that when related to current literature enables the reader to assess its transferability to other groups (Pringle et al, 2011).

In addition to the studies by Clare above, IPA has been used successfully many times in research involving people with dementia and their carers, including to explore how older women living alone with dementia managed their identities and coped with day to day living (Frazer et al,2011), to explore the appraisals and coping processes of men who have early-

stage Alzheimer's disease (Pearce et al 2002), to explore cause and control illness representations in Alzheimer's disease (Matchwick et al, 2013), to explore experiences of receiving a diagnosis and adjusting and adapting to dementia (Lee et al 2014) and to explore the subjective experiences of personhood in dementia care settings (Nowell et al 2011).

4. RESEARCH QUESTION/AIM(S)

4.1. Objectives

The overall objective of this study is to explore whether receiving a diagnosis of dementia during a hospital admission, when you have not sought help previously, comes at the right time for the person diagnosed and the carer of a person diagnosed. The specific research questions are:

1. How do people perceive the timeliness of a diagnosis of dementia made during an acute hospital admission and does this change over time?
2. How do people perceive their memory problem (or that of the person they care for) prior to hospitalization and does this influence their help seeking decision making process?
3. What are the factors that influence the subsequent decision not to seek professional help?
4. Are there differences between people with dementia and carers in the timeliness and meaning of the diagnosis and perspectives on help seeking?
5. Does this group of people diagnosed with dementia and carers of those diagnosed differ, in regards to their help seeking decision making process and the meaning of the diagnosis, to those who do seek help as reported in the literature?

4.2. Outcome

The broad outcomes for this study will be to understand whether receiving a diagnosis of dementia during an acute hospital admission came at the right time for the person diagnosed and for the carer of a person diagnosed – both their perspective at the time of diagnosis and whether this had changed three- six months later. In addition it will be to understand why they had not sought help previously for their dementia symptoms and to explore what factors, if any, had an influence on their decision making process.

5. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

This is a qualitative study using Interpretative Phenomenological Analysis (IPA) and will employ in depth, semi structured interviews as a data collection method. To produce the rich data that IPA requires, participants will need to be able to speak freely and reflectively in order to tell their story and express their thoughts and feelings (Smith et al 2009). In depth interviews are the most appropriate data collection method to facilitate this. Cowdell (2008) found that during the course of her research to explore the experiences of people with dementia in acute

hospital, that participants conversed more readily and the data collected was richer when people were enabled to talk, rather than being asked questions.

5.1 Interviews

All participants will be invited to take part in two interviews. The first interview will take place in the first few weeks after diagnosis. This increases the likelihood of the person with dementia and carers remembering what they thought of any signs or symptoms of dementia prior to the hospital admission and will enable an exploration of their first thoughts about whether the diagnosis has come at the right time for them. The second interview, between three and six months later, will explore whether their thoughts about the symptoms have changed since diagnosis and whether receiving the diagnosis when they did has been of benefit to them and would be considered timely or not.

If at the time of the second interview, the person with dementia or carer no longer wished to take part, the researcher will confirm that they are happy for the data collected in their first interview to continue to be used in the study.

All interviews will be conducted, in person, by the chief investigator and with the permission of the participant they will be audio recorded. Note taking will be kept to a minimum to avoid disrupting the flow of conversation between the researcher and participant, but will be used to record any specific issues relating to process consent (see section 7.2.2).

5.2 Interview schedule

An interview schedule will be used to guide the content of the conversation, although participants will be encouraged to talk about any aspect of the topic that is important to them and in whatever order they feel most comfortable. An interview schedule is likely to be useful when interviewing people with dementia who may need increased prompts to remind them of the topic and encouragement to continue talking. Hubbard et al (2003) reflecting on the challenges of interviewing people with memory impairment found that, at times, minimal intervention from the researcher meant the person with dementia was left struggling to develop the conversation themselves, possibly causing embarrassment. They recommend finding a balance between privileging the voice of the person with dementia and ensuring they feel supported. The use of an interview schedule could help to ensure this balance is met. Although the chief investigator has extensive clinical experience working with people with dementia, she is a novice researcher, and an interview schedule is likely to reduce anxiety, thereby improving the flow of the interview and giving the participant increased confidence in the researcher.

Four interview schedules have been designed – one for each of the two interviews with the person with dementia and one for each of the two interviews with the carer. The schedules have been developed based on the research questions and guidance on constructing an interview schedule for IPA studies (Smith et al 2009). The interview guides were reviewed by people with dementia and their carers at the Waltham Forest Alzheimer's society Dementia café. All those who reviewed the questions felt that they were appropriate for the topic of the study, not too intrusive or sensitive and felt that they would be happy to answer these. A summary of the topics in the interview guide is included in the participant information sheet so that participants know the topics they will be asked to discuss in advance.

5.3 Data Analysis

5.3.1 Transcription

All interviews will be audio recorded and then uploaded onto a password protected university computer at the earliest opportunity. The audio recordings will be transcribed by the researcher only and the transcriptions will be stored in an encrypted file on a password protected university computer.

At the time of interview each participant will be given a unique identifying code consisting of a letter, which signifies the participant and then a number which signifies that it is their first or second interview e.g. A1, A2, B1, B2 etc. A separate electronic document will be kept in an encrypted file on a university password protected computer which links the unique codes to the participant's name. Only the researcher will have access to this in order to ensure that the same letter codes are used for each participants first and second interviews and to facilitate sending a copy of the transcription to the participant for member checking if they so wish.

Interviews will be transcribed in keeping with guidelines for IPA studies (Smith et al 2009). Transcripts will include all the words spoken by everyone present including notes of any non-verbal utterances, laughter, significant pauses or hesitation.

At the time of transcription all interview transcripts will undergo pseudonymisation to ensure that individuals cannot be identified from their interview transcripts or any quotes used from them. This will include removing all names from the transcript and replacing them with a pseudonym or a tag that typifies the person e.g. daughter, husband, friend, neighbour. Also any exact geographical locations which could be used to identify someone will be replaced with a meaningful descriptive term. Guidance provided by the Information Commissioners Office (2012) in the Anonymisation Code of Practice will be used to ensure that it is highly unlikely that any individual could be identified from any published results or findings (see section 8.1.2 for further discussion on transcripts and confidentiality).

5.3.2 Analysis of data

Analysis of the transcripts for each participant will begin after the first interview has taken place and completed after the second interview has taken place.

IPA analysis is an iterative process and can be open to change, but the novice student researcher using IPA is recommended to follow a step by step approach (Smith et al 2009). The researcher will carry out the analysis of the data herself and the analysis will be done manually, without the aid of qualitative data software, to enhance the learning process and develop data analysis skills.

Analysis of the interview transcripts will follow the six steps of analysis in IPA as outlined by Smith et al (2009). In keeping with the idiographic principles of IPA, each case (i.e. the two interviews of each participant) will be analysed in detail individually and then in the final stage of analysis, patterns across cases will be explored e.g. patterns across interviews with people with dementia, patterns across interviews with carers. Only the overall themes from the group of people with dementia and the group of carers will be compared and contrasted. No links will be made between individual people with dementia and their carer.

Stage 1 Reading and re-reading – the researcher reads the individual interview transcript whilst listening to the audio recording in order to become familiar with and engage with the data.

Stage 2 Initial noting – the researcher makes initial notes in the margin on anything of interest e.g. key words or phrases highlighting things that are important to the participant, content and meaning of the language used, questions arising about what the participant may mean.

Stage 3 Developing emerging themes – the researcher begins to look for connections, interrelationships and patterns between the exploratory notes made in stage 2 to develop emerging themes

Stage 4 Searching for connections across emergent themes – the researcher maps or charts the emergent themes, looking for patterns or connections between them and possibly creating clusters of themes under a superordinate theme. A graphic representation of the structure of emergent themes is made, annotated with quotes or words from the transcript to demonstrate each theme.

Stage 5 Moving to the next case – Stages 1-4 are repeated for the next participant's interview transcript, allowing new themes to emerge with each case.

Stage 6 Looking for patterns across cases – the graphic representation of themes for each participant is laid out to enable the researcher to identify similarities, differences and patterns across the cases. This may involve relabeling or reconfiguring themes and will lead to the production of table of themes for the group, showing how themes are nested within super-ordinate themes and illustrated with quotes from interview transcripts.

5.3.3 Data Storage

During the course of the study the audio recordings, interview transcripts and stages 4 & 6 of the data analysis will be stored electronically in separate encrypted files on a networked drive on a university password protected computer that only the researcher has access to. This will ensure that data is backed up regularly and stored securely minimising the risk of loss, theft or unauthorised use.

Hand written notes from the interview and stages 1-6 of the data analysis will be stored in a locked filing cabinet at the university that only the researcher has access to.

All data will be stored in accordance with the Data Protection Act (1998) and the City, University of London Data Protection Policy for 10 years after the study has finished.

6. STUDY SETTING

The setting for the interviews in this study will be a place of the participant's choice. This is likely to be their own home, but could also be an alternative community setting of their choosing. Barts Health NHS Trust will act as the participant identification centre for the study. Potential participants will be approached and given information about the study during their hospital admission (or the hospital admission of the person they care for) but their consent to participate and the interview will take place after the person diagnosed with dementia has been discharged from hospital (see section 7.3 for details on identification and recruitment).

Carers who are potential participants will be contacted by telephone to discuss their own participation. If they are happy to take part or would like to discuss the study further the researcher will arrange a date and time to visit them. As only people with dementia who have a main carer/ next of kin will be eligible to take part, the researcher will discuss with their carer how best to contact the person with dementia to discuss the study and will be guided by the carer as to when and how to contact them. Although some people with dementia will be able to give fully informed consent to taking part, it will be important for their main carer/ next of kin to also be happy for them to participate. James McKillop, a person with dementia who has taken part in numerous research interviews, advises that although the person with dementia is an individual who should be given the choice to participate themselves, carers should be consulted and interviews should only go ahead if they are also reassured - "if anything goes wrong, they are left to pick up the pieces" (McKillop & Wilkinson 2004).

It will be important to ensure that participants feel comfortable and at ease during their interviews which may last for a considerable amount of time. Interviews with carers are likely to last between 60 – 90 minutes. Interviews with people with dementia are likely to last around 30mins. Participants will be encouraged to tell the researcher if they are feeling tired or uncomfortable during the interview. If they begin to feel tired or for any other reason feel they cannot complete the interview in one sitting, the researcher will offer them a break or offer to return on another day to complete the interview.

Allowing the participant to choose the setting for their interview is thought to reduce the power imbalance between participant and researcher (Clarke, 2006), increasing the control participants feel they have over the process. In turn they are likely to feel more relaxed and able to engage in the interview. If the participant chooses to be interviewed in a setting away from their home (or their carer's home) all efforts will be made to ensure there is a quiet, private space which will be free from interruptions. The person with dementia will be given the option of having their carer present during the interview if this helps them to feel more comfortable, although the carer will be asked not to participate in the person with dementia's interview. Carers will be interviewed on their own with the researcher.

7. SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

In order to answer the research questions, the study population will be people who have been diagnosed with dementia during an acute hospital admission and carers/ next of kin of people who have been diagnosed with dementia during an acute hospital admission. Potential participants who do not speak English sufficiently to be able to participate in an in-depth interview will not be eligible for the study.

It is acknowledged that this is not ideal and that by excluding people who do not speak English I may overlook important meanings in the timeliness of diagnosis and that the meaning of diagnosis and timeliness may be different for those who don't speak English compared to those who do.

As this study aims to explore the meaning of receiving a diagnosis of dementia for an individual, the qualitative data generated will require more than a verbatim translation of words but would need to incorporate ethnic and cultural understandings. To achieve this would require a translator experienced in conducting qualitative interviews, who also has some understanding of the cultural

background of the participant. Unfortunately the cost of such interpreters is beyond the scope of this non-funded student research study. However it is considered that meaningful data can still be gathered.

This study aims to be able to give a complete account of the perceptions of people with dementia and their carers on the timeliness and meaning of their diagnosis, but acknowledges that people in the more severe stages of dementia or those nearing the end of life may be less willing or able to participate. The researcher feels that it is important that they are offered the opportunity to participate, should they so wish, so they will be approached about the study unless their carer/ next of kin feels that they would not wish to or be able to participate.

Only people who have been informed of their diagnosis and the diagnosis of the person they care for will be approached about the study. As the study is specifically seeking their thoughts and experiences on receiving a diagnosis during the hospital admission, anyone who has not had a formal feedback of the diagnosis from their clinician will be excluded.

As described previously (section 6) it is considered best practice to consult a carer/ next of kin of a person with dementia prior to taking part in research and in the case of those people who may lack capacity to consent, a personal consultee would be preferable to a nominated consultee. So for this reason if the person diagnosed with dementia has no carer/ next of kin, they will not be included in this study.

It is not necessary for both the person with dementia and their main carer/ next of kin to participate, although if both are willing to participate they will both be included.

7.1.1 Inclusion criteria

INCLUSION CRITERIA People with Dementia:

- People of any age diagnosed with dementia, of any sub type, during an acute hospital admission to Barts Health NHS Trust
- Have been informed of their diagnosis during their hospital stay
- Have a named informal carer or next of kin
- Able to give consent or have a carer or "consultee" who can give agreement for participation
- English language sufficient to be able to participate in an interview

INCLUSION CRITERIA Carers:

- Main informal carer or next of kin of a person diagnosed with dementia, of any sub type, during an acute hospital admission to Barts Health NHS Trust
- Have been informed of the diagnosis during the hospital admission
- Able to give written informed consent
- English language sufficient to be able to participate in an interview

7.1.2 Exclusion criteria

EXCLUSION CRITERIA:

- People who have not been informed of their diagnosis
- People diagnosed with dementia who have no named carer or next of kin

7.2. Sampling

This section will explain and justify sampling in terms of volume and technique.

7.2.1 Size of sample

The focus of IPA studies is a detailed examination of a complex human phenomenon, in this case the experience of receiving a dementia diagnosis during a hospital admission. For this reason IPA studies usually benefit from a smaller sample which can be explored in depth rather than a larger sample, for which the data collection and analysis could be overwhelming and the results more superficial (Smith et al 2009).

There is no set sample size for an IPA study and although a sample of between three and six participants is thought to be reasonable for a student IPA study (Smith et al 2009) a sample of ten participants is recommended as the target for a PhD study (Smith, 2016). It is also recommended that IPA PhD studies have an added layer of complexity and this study will achieve this by interviewing participants at two different time points and attempting to understand the experience from different perspectives - the person with dementia and carers of people with dementia.

As recommended by Smith (2016 – see section 8.4 Peer Review for details), this study will aim to have a sample of between 5-6 people with dementia and 5-6 carers/ next of kin.

The sample size is also in keeping with the numbers of people diagnosed with dementia in hospital, which is generally small (around 10 per month at Barts Health).

However the sample size will also be governed by the quality and richness of the data gathered in the initial interviews. Qualitative research study sample sizes are often justified on the basis of reaching theoretical saturation (Kelly, 2010). If the data collected in the initial interviews is limited then the sample size may be increased in order to ensure there is sufficient meaningful data for analysis.

If the number of people with dementia willing to participate is not sufficient to gather meaningful data for analysis other options will be considered, which could include increasing the number of carers recruited to a minimum of ten.

7.2.2 Sampling technique

My chosen participant identification centre, Barts Health NHS trust, includes three district general hospitals and one specialist centre covering a wide geographical area of east London. However the number of people who receive a diagnosis of dementia during a hospital admission is relatively small. Data from a service evaluation I conducted as part of my PhD studies showed that the people who receive a diagnosis of dementia in hospital tend to be older and have more physical health problems than people diagnosed via an outpatient memory clinic, both of which may limit the number of people who are willing and able to take part. For these reasons I intend to use the method of convenience sampling initially. In this case all those who meet the inclusion criteria will be approached to participate in the study.

Although this method of sampling could be considered to be the least analytically strong option (Rapley, 2014), this should allow me to recruit a sufficient number of participants to begin to understand some of the key issues relating to the timeliness of a diagnosis made in hospital.

As analysis of the data will begin as each interview is transcribed there will be the opportunity to identify emergent themes from the initial interviews that warrant further exploration. In this instance, if there are sufficient numbers of potential participants, the sampling technique can be refined to purposeful sampling - "selecting information rich cases to study, that by their nature and substance will illuminate the inquiry question being investigated" (Patton, 2015 p264). This would be in keeping with the orientation of IPA and of its iterative and practical nature. Specifically this could be described as analytically focused sampling (Patton 2015), selecting cases to elaborate and deepen the initial analysis that either add to or confirm understanding of emerging findings or variations and exceptions to emerging findings.

7.3 Recruitment

Barts Health NHS Trust will be the participant identification centre for this study. Barts Health NHS Trust is the largest NHS trust in the UK serving a population of 2.5 million people in east London. The trust has two large district general hospitals (Whipps Cross University Hospital and Newham University Hospital) and two large specialist centres (The Royal London Hospital & St Bartholomew's Hospital), one of which also provides local services.

Each of the four hospitals has a Dementia and Delirium team. These teams consist of clinical nurse specialists, therapists and support workers whose clinical background and expertise is in caring for people with dementia. The teams work closely with the psychiatric liaison teams on each site who assess, diagnose and provide advice to patients with a wide range of mental health needs.

Patients will be admitted to hospital for a wide variety of acute medical and surgical problems and as part of their initial and ongoing care many patients will undergo some form of cognitive screening to identify potential acute or chronic cognitive impairment. If a patient is suspected of having a cognitive impairment they are usually referred to the psychiatric liaison team for assessment. In most cases following an initial assessment they will be referred to a local memory clinic for further investigations and follow up. But in some cases they may receive a diagnosis of dementia whilst they are still in hospital.

The clinical nurse specialists in the Dementia and Delirium (DAD) teams aim to see all the people who receive a diagnosis of dementia in hospital to provide post diagnosis support and information to the person diagnosed and to their carer or next of kin. This usually involves seeing the person diagnosed and their carer on several occasions between diagnosis and discharge from hospital and coordination with community services where necessary.

7.3.1 Sample identification

Potential participants (people with dementia and carers) will be identified by the clinical nurse specialists in the DAD teams at each hospital. All patients who are referred to them by the psychiatric liaison team, as having received a diagnosis of dementia whilst in hospital, will be approached about the study if they meet the inclusion criteria. The main carer/ next of kin of all people diagnosed with dementia in hospital will also be approached about participating. As the nurses from the DAD team will be seeing the person diagnosed and their carer as part of their clinical role and as part of the existing clinical care team for the patient, they will have

access to the patients records without requiring explicit consent, in order to be able to determine if the person has a carer or next of kin and if they are able to speak English sufficiently well enough to take part in an interview.

Full training will be given to the DAD teams by the researcher to ensure that they understand the inclusion/ exclusion criteria and are able to explain basic details of the study to the person diagnosed and carers of people being diagnosed. The DAD teams have received training from Join Dementia Research (a service run by the NIHR and Alzheimer's society which allows people to register their interest in participating in dementia research and be matched to suitable studies) to increase their confidence and skills in talking to people with dementia about taking part in research studies and are encouraged to do this as part of their role.

Once potential participants have been identified, the nurses will ask permission of the carer/ next of kin to pass on their contact details (name and telephone number) to the researcher, so they can be contacted to discuss the study further. It may also be possible for the researcher to visit the person diagnosed and their carer whilst they are still in hospital so they can be personally introduced by the DAD team to discuss the study further, if the person with dementia or their carer so wish. This may serve to reduce anxiety associated with meeting the researcher in person for the first time at the time of the interview.

Personal details of potential participants – names and contact numbers – will be passed on to the researcher by the DAD team in person or via telephone. They will not be sent by email/ voicemail to reduce the likelihood of a breach in confidentiality.

Participants will be interviewed at a venue of their choosing, which is likely to be their own home or their carer's home. Alternatively if the participant attends a day centre, dementia café or other community setting the interview could take place there if a quiet and private space can be located. Consequently participants will not be expected to travel to interviews and no payments to participants are expected.

According to IRAS guidance, in non-clinical studies it is a matter of judgement whether the participants GP is informed that they are taking part in a study. After careful consideration the researcher has decided not to routinely inform participant GP's in this study. There are understandable reasons for a GP to be aware that a patient of theirs with dementia is taking part in a research study e.g. to know that someone is visiting the person at home, in the event that the person speaks about or asks the GP about the study and as an additional gatekeeper or safeguard to protect the person with dementia from harm. However, in this study, no person with dementia will be approached without their carer or next of kin's permission and their carer or next of kin will be fully informed of the study in addition to the person with dementia. Therefore it is felt that this provides a sufficient safeguard for the person with dementia and that in many cases the carer or next of kin would be present if the person was visiting or being visited by their GP, in order to explain or discuss their participation if they wished too. Also as this is a qualitative study exploring the meaning and timeliness of receiving a diagnosis of dementia in hospital, the study will not in any way influence the care or treatment the person with dementia receives. As part of understanding the timeliness of the diagnosis, the reasons why the person had not sought help prior to admission to hospital will be explored. As previous research has found, reasons for delaying help seeking in dementia include previous bad experiences with

health care services (Werner, 2014) which may include previous experiences with primary care services and the person's GP. It is possible that even if the person was reassured that their GP would not have access to the data they provide, they may not be willing to take part or may not feel they can be honest about their reasons for not seeking help if they know their GP has been informed of their participation. IRAS guidance also states that if a participant refuses permission to approach their GP they should be excluded from the project. As the study population in this project is already small and can be considered a hard to recruit group, excluding participants on the basis of them not wanting their GP to be informed could significantly affect recruitment to the study. However if during or following an interview, a participant has appeared distressed or expressed a need for further support and information, the researcher plans to refer the participant back to the DAD team for community follow up to be arranged or will leave contact details for local services with the participant. In these circumstances the researcher will ask the participants permission to inform their GP of the referrals made/ information given so that their GP can also support them if necessary and to put in place a safeguard in the event that follow up from an onward referral does not take place.

7.3.2 Consent

Informed consent will be sought from all participants but it is acknowledged that some of the people with dementia who are eligible to take part will lack the capacity to give fully informed consent or may lose capacity to give informed consent between the first and second interviews. For this reason, the consent process for this study has been developed to comply with the Mental Capacity Act (2005) (section 30-34) and with process consent methodology (Dewing, 2007), which is considered best practice when conducting research with people with dementia. Although one of the secondary research questions in this study is to determine whether there are differences in the meaning of receiving a diagnosis between people with dementia and carers of people with dementia, the researcher will ensure that potential participants understand that it is not necessary for both the person diagnosed and their carer to be willing to participate in order to be included in the study. It is important that either the person with dementia or their carer do not feel obliged to take part because the other wishes to do so (Forbat & Henderson 2003) and that the contribution of one or the other will be very valuable if both are not willing or able to participate.

Consent Process for carer participants

The following process will apply to all carers/ next of kin who are willing to participate.

- The carer/ next of kin will have received an information leaflet about the study from the DAD team in the hospital and will have given permission for their contact details to be passed on to the researcher. They will have had the opportunity to ask the nurse in the DAD team any immediate questions and in some circumstances will have had the opportunity to meet the researcher to discuss the study further.
- The researcher will contact the potential participant by telephone to discuss participation in the study, answering any questions they have at this stage and arrange a time to visit the participant.
- During the first visit to the participant, at their chosen venue, the researcher will go through the study information leaflet with the participant, giving further explanation

where necessary and answering any questions the participant has. All efforts will be made to address any sensory needs of the person including providing the information leaflet in large print. The researcher will ensure that the person understands that the interview will be audio recorded, that transcriptions of the interview and any quotes from the interview used in publications will be anonymized. The researcher will also ensure that they understand they can withdraw from the study at any time.

- If the carer/ next of kin is willing to participate the researcher will then give them a copy of the consent form and talk through the sections on the form, answering any questions the participant has.
- If they are still willing to participate, the researcher and participant will sign two copies of the consent form and the interview will proceed. The researcher will retain one copy of the consent form and the participant the other.
- At the time of the second interview, the same process will be followed. If at this time the carer/ next of kin no longer wishes to participate the researcher will confirm that they are still happy for the data provided in their first interview to be used.

<u>Consent Process for people with dementia</u>

The following process will apply to all people with dementia who are invited to participate.

- The person with dementia will have received either the brief summary information sheet or the full information sheet about the study from the DAD team in hospital and will have been encouraged by the DAD team to discuss the study with their carer/ next of kin (who will have received the full information sheet as above) or others. They will have had the opportunity to ask the nurse in the DAD team any immediate questions and in some circumstances will have had the opportunity to meet the researcher to discuss the study further.
- At the time of contacting the carer/ next of kin by telephone to discuss their own participation in the study, the researcher will ask the carer/ next of kin if the person with dementia is still likely to be willing to take part or would like more information about participating in the study. If they would, the researcher will ask the carer/ next of kin if the person with dementia would like to be contacted by the researcher or if the carer would prefer to make the arrangements for the researcher and person with dementia to meet.
- The researcher will answer and address any concerns the carer may have about the person with dementia participating in the study. The researcher will explain that they will carry out an assessment of the person's capacity to consent and that if they are felt to lack capacity to consent, the carer will be asked to act as a consultee. The role of the consultee will be explained to the carer in advance. The process consent methodology will also be explained to the carer. If the carer is happy for the researcher and person with dementia to meet, they will arrange a time to contact/ visit the person at their chosen venue. The carer will have the option of being there as well there if they and the person with dementia so wish.
- During the first visit to the person with dementia the researcher will go through the study information leaflet with the participant, giving further explanation where

necessary and answering any questions the participant has. All efforts will be made to maximise the ability of the person with dementia to understand the information about the study in order to give informed consent e.g. the use of props to help explain the interview procedure e.g. showing the person the Dictaphone and how it works.

- Throughout the explanation of the study and following the explanation the researcher will assess the capacity of the person with dementia to give fully informed consent, based on the criteria outlined in the Mental Capacity Act (2005). In order to be considered to have capacity the person must be able to demonstrate that they understand the purpose and nature of the study, what they will be expected to do and any possible risks this may have for them. They must be able to demonstrate that they understand that they do not have to take part and can withdraw at any time. They will need to be able to make a decision about whether to participate and communicate this to the researcher.
- If the researcher feels that the person has the capacity to give consent they will then give them a copy of the consent form and talk through the sections on the form, answering any further questions they have. If the researcher is still happy that they have capacity to consent the researcher and participant will sign two copies of the consent form and the interview will proceed. The researcher will retain one copy of the consent form and the participant the other.
- If the person with dementia is judged not to have capacity to consent then the researcher will ask their carer/next of kin if they are happy to act as a "personal consultee". If the carer/next of kin are present at the time, they will be given an information sheet about the role of the personal consultee and the researcher will answer any questions they have. They will be asked to consider the person with dementia's prior wishes or thoughts regarding taking part in research. If they are happy to act as a consultee and happy to give assent to the person they care for taking part, they will be asked to sign a consultee assent form. Once assent from the consultee has been gained the interview will continue as planned using the method of process consent (see below). If the consultee does not give assent then the interview will not take place and the person with dementia will be withdrawn from the study.
- If the carer wishes to take time to consider acting as a consultee or take time to consider what the person with dementia would want, then the interview will not go ahead and the researcher will arrange to contact the carer within the following few days to ascertain whether they are happy to give assent for the interview to go ahead. If the consultee does not give assent then the interview will not take place and the person with dementia will be withdrawn from the study. If the carer does not wish to act as a consultee, but feels that the person with dementia would want to take part, then the researcher will ask if there is anyone else that could act as a consultee and will make arrangements to contact them to discuss the person with dementia's participation in the study and the role of consultee, as above.
- If the carer/ next of kin is not present at the time of the capacity assessment, the researcher will contact them by telephone. The role of the personal consultee will be explained to them and verbal assent will be requested. A copy of the information sheet and consultee assent form will be sent to them in the post. If verbal assent is given the interview will continue as planned using the method of process consent. If after two

weeks the consultee has not returned the signed assent form they will be contacted by the researcher or sent a reminder by post. If the consultee does not return the assent form or changes their decision, the person with dementia will be withdrawn from the study and any data that has been collected will be destroyed. If the carer/ next of kin wishes to take time to consider acting as a consultee or to consider what the person with dementia would want then the process in the bullet point above will be followed.

- At the time of the second interview, the same process will be followed. If at this time the person with dementia no longer wishes to participate or their consultee no longer wishes them to participate the researcher will confirm that they are still happy for the data provided in their first interview to be used.

Process Consent

The process consent method (Dewing 2007) is considered best practice when conducting research with people with dementia who lack capacity to give informed consent, but who are able to communicate their wishes in other ways and ensures that the person with dementia remains at the centre of the process at all times. It is also thought to add credibility to the informed consent process, ensuring that judgements made by the researcher about capacity and consent are open and transparent. Where informed consent from a person with dementia has been obtained, the process consent method will also be used to ensure the interests of the person with dementia are protected and prioritised at all times.

There are five stages to the process as outlined below, along with how the researcher intends to carry out each element within this study.

Stage 1 Background and preparation - When the researcher contacts the main carer/ next of kin to discuss participation of the person with dementia in the study they will ask about the person and any specific issues important to the interview process e.g. how the person usually communicates best, which times of the day, how long they are comfortable talking for, what environment they would be most comfortable being interviewed in, any sensitive topics that could distress the person, so that these can be avoided. The researcher will find out how the person usually makes choices and how they consent to activities or procedures in everyday life.

Stage 2 Establishing basis for consent - Capacity to consent will be established as described previously.

Stage 3 Initial consent – After establishing capacity to consent the researcher will again ascertain whether the person with dementia is happy to participate in the interview. This will involve listening to what the person has to say but also taking account of any non-verbal signals (facial expression, body language) that may suggest how the person is feeling. The researcher will use the Bradford Dementia Group Well Being Profile (2008 – Appendix 3) of positive and negative behavioural indicators (verbal and non-verbal communication and emotions to determine how a person with dementia might be feeling) along with information already gained from the carer/next of kin to make a judgement as to whether the person is consenting to the interview or not. The researcher will make notes on the signs observed, as part of the record that the person was giving consent or not.

If in the opinion of the researcher/ consultee the person with dementia is not consenting to the process, the interview will not proceed and the person will be excluded from the study.

Stage 4 On-going consent monitoring – Throughout the interview the researcher will closely observe for any changes in the verbal or non-verbal behaviour of the person with dementia and compare this to the behavioural signs the person showed when they made initial consent. The researcher will do this for all participants with dementia, even those who were able to give informed consent, in case their capacity is fluctuating. If the researcher feels that the person's behaviour has changed then the interview will terminate and the initial consent process will begin again, if appropriate, or the interview will be terminated completely. If the carer/consultee is present then the researcher will also seek their opinion and advice as to whether the interview should continue or not. If the interview is terminated because it is felt the person with dementia is no longer consenting to the process, then the person will be excluded from the study and any data collected at this time will not be used. Clear documentation will be made by the researcher of the signs observed and any decisions made to continue or terminate the interview, along with the outcome of any revisited consent process.

Stage 5 Feedback and support - The content of the interview will remain confidential unless the person with dementia expressed a wish for any information to be shared with their carer/ consultee at the initial consent stage. However the researcher will give feedback to the carer/ consultee on how the person fared during the interview and on any concerns the researcher has about the person's well-being. At the end of the interview the researcher will ensure that the person with dementia is comfortable and happy before leaving them, this could include spending some time engaging in social conversation, helping to make a drink with them to help readjust from the research context back to their everyday life. If the researcher feels that during the interview the person with dementia has raised issues around support or information needs, the researcher will discuss how these could potentially be met.

8. ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Ethical Considerations

There are a number of ethical considerations in undertaking this study which include involving people with dementia in research, including people who lack capacity to consent and the use of in depth interviews. This section will address each of these areas explaining how this study intends to address them.

8.1.1. Research involving people with dementia

Until the late 1990's the majority of research aimed at understanding the experience of living with dementia focused on the views of carers and family members (Murphy et al 2015). However previously held beliefs that people with dementia were unable to express their views and opinions has been challenged and increasingly people with dementia started to be included in research (Wilkinson 2002). This revealed that often the views and experiences of carers and family members, although very useful in its own right, differed from those of the person living with dementia (Murphy et al 2015), further reinforcing that we cannot know what people with dementia want or need without seeking their views and experiences

(Wilkinson, 2002). As a result research methods that are acceptable to people with dementia and practical issues around how to include people with dementia in research are increasingly being written about and critiqued (Cowdell, 2008, Murphy et al 2015).

It is important that people with dementia are given the opportunity to participate in research if they wish. If we are to truly understand the needs of people with dementia with regards to when and whether a diagnosis is important or of benefit to them, then we need to include them in research so that their voice is heard. As the views of people with dementia may differ from those of carers it is essential that we include people with dementia as well as carers in this study.

But consideration needs to be made of the possible vulnerability of people of dementia as they take part in research, regardless of their ability to give informed consent. Although it is a requirement of the Mental Capacity Act (2005) that the views of carers or other relevant people are sought before including someone who lacks capacity in research, the role of gatekeepers (e.g. carers, family members, staff involved in caring for or approaching participants about research) are often crucial at the recruitment stage of a study and beyond, regardless of the whether participants have capacity to consent. The perception of carers and staff towards research involving people with dementia in general and their feelings about a particular study can greatly influence the access to and involvement of people with dementia in a study. However this form of protection for people with dementia is necessary (McKeown et al, 2010) and from the point of view of the person with dementia is also desirable (McKillop & Wilkinson 2004).

In this study the involvement of the carer/ next of kin will be essential in negotiating first contact with and access to the person with dementia. It is important that the carer/ next of kin understands not only their own role in the study (if they wish to participate) but also the importance of gathering the views of the person they care for, in addition to the practical aspects of how capacity, consent and the interview itself will be conducted. It is the view of the researcher that the carer in this study, needs to be reassured and happy with the research process in order to maximise the engagement of the person with dementia. For this reason, time will be given to ensuring that the carer/ next of kin is fully informed and has the opportunity to ask questions and talk to the person they care for about the study, before the researcher approaches the person with dementia about their participation. Gathering information about the person with dementia (e.g. how and when they usually communicate best, how they consent to activities on a day to day basis) before meeting with them is considered best practice (Murphy et al 2015) and will be a key part of the initial contact with carers in this study. Also as part of the process consent method, carers will be kept up to date about how the person with dementia fared during and after the interview, to reassure them.

Paternalistic views of staff caring for people with dementia may prevent them from introducing them to studies the person may be interested in (McKeown et al, 2010). The nurses in the dementia and delirium teams at Barts Health are receiving training from Join Dementia Research to help them understand the benefits of involving people with dementia in research and to increase their confidence in approaching people about research. In addition to this the researcher will provide a group and one to one sessions on the details of this study and their roles in participant identification to ensure they feel positively about the aims of the study and confident that they can introduce the study to their patients and carers.

Another key concern in involving people with dementia in research is that those who undertake the research should be experienced in working with and communicating effectively with people with dementia (Hubbard et al 2003, Hellstrom et al 2007). The researcher has twenty years' experience working with people with dementia and communicating with people at all stages of dementia as a general nurse working in older people's care settings and in her most recent role as a nurse consultant for older people and dementia. This role involved assessing and working with people who were being diagnosed with dementia during a hospital admission and with people with advanced dementia and their carers and families towards the end of life. This will enable her to be responsive to the needs of the person with dementia during the interview process, including responding to needs expressed verbally and non-verbally. The Bradford Wellbeing profile (Bradford Dementia Group, 2008) is a recognised tool to monitor how people with dementia are faring psychologically and socially both in care settings and in research (McKeown et al 2010). The researcher proposes to use this tool to monitor the well-being of the person throughout the interview and as part of the process consent method to enhance the transparency of any judgements made regarding capacity and consent. The researcher is familiar with using the tool and interpreting the behavioural indicators in clinical practice.

A final issue that is often debated when including people with dementia in research is whether to use the term "dementia" or not (Reid et al 2001). There can be concern that if the researcher uses the term first they may inadvertently give someone a diagnosis they did not know they had or had forgotten they had, causing unnecessary distress. Others argue that if the research process is to be open and transparent then this must extend to the use of the term dementia as well (Bartlett & Martin 2002, Mckeown et al 2010). Most often alternative terms such as "memory problems" are used unless the person says that they have dementia, in which case, it is then felt appropriate for the researcher to also use this term (Hellstrom et al 2007). In this study only people who have had a formal feedback of their diagnosis will be included, so all the people with dementia participating will have been told they have dementia. However, at the time of their interview it is possible that they may not remember their diagnosis or for whatever reason are in denial or do not want to acknowledge their diagnosis by name. So in keeping with previous research, the researcher will only use the term dementia/ Alzheimer's disease during the interview if the person with dementia mentions it first. The term memory problems will be used otherwise.

8.1.2 In depth interviews

In depth interviews are often seen as the method of choice for data collection in studies involving people with dementia (Murphy et al 2015). Difficulties answering direct questions can be overcome by engaging the person in a conversational style interview, allowing them to direct the flow of the interaction with guidance and prompts from the researcher. It is thought that this enables the person with dementia, as well as helping to gather richer data (Cowdell, 2008). As interviews with people with dementia are often aimed at exploring their views and experiences of things that have already taken place, there is often very little direct benefit to the person from taking part. According to the Mental Capacity Act Code of Practice (Dept. of Constitutional Affairs 2007), research that involves people who lack capacity must either have some chance of benefiting the person who lacks capacity or provide knowledge about the cause, treatment or care of people with the same or a similar condition.

As this study aims to explore the experience and timeliness of receiving a dementia diagnosis and the help seeking decision making process that participants have already been through, any insight gained into how the experience could be improved for others will have no direct benefit for the participants. In this case it is essential that the study meets the subsequent requirements of the Mental Capacity Act (2005) - the risk to the person must be negligible, there must be no significant interference with their freedom of action or privacy and nothing must be done which is unduly invasive or restrictive.
It is in the opinion of the researcher that the risk posed by taking part in this study is negligible, does not interfere with the freedom of action or privacy of the person and is not unduly invasive or restrictive.

The interview schedules devised for the study were reviewed by people with dementia and their carers at Waltham Forest Alzheimer's Society dementia café. Their opinions were, that the topic itself and the questions and prompts proposed were not too sensitive or intrusive and they would be happy to discuss them in a research interview. The venue for the interviews will be determined by the participants, so the researcher will only be visiting people in their own homes at their request. If the person does not wish to be interviewed in their own home, all efforts will be made to find an alternative venue that fits with the usual routine of the person e.g. day centre, dementia café, community group.

There are concerns that taking part in interviews may cause psychological distress when talking about and reliving difficult life experiences, that participants worry about breaches in confidentiality when sharing personal information or concerns that participants may reveal more than they intend to within an interview situation and later regret this (Corbin & Morse 2003, Clarke 2006). However it is thought that by engaging people well during an interview they can exercise considerable control over the process themselves, deciding what they do and don't talk about and how things are said (Hutchinson et al 1994, Corbin & Morse, 2003). Concerns about upsetting participants and breaches in confidentiality also assume that the risk of this happening is greater in a research interview than it is if the person were discussing the topic with family or friends (Corbin & Morse 2003). Yet a researcher may be more likely to be interested in how the person feels and be empathetic, than family and friends would be and the researcher will have rigorous processes in place to prevent breaches in confidentiality e.g. anonymising data (Corbin & Morse 2003). There may also be benefits to the participant in talking about their experiences e.g. feelings of relief in being able to express how they feel to someone who is engaged and ready to listen, validation of their feelings, an increased sense of self-esteem and purpose and feeling empowered by having their voice heard (Hutchinson et al 1994). Also knowing that sharing their story may help others in the future is often a reason for people to wish to take part (Clarke 2006, Corbin & Morse 2003).

People with dementia and their carers who were consulted about the topic of this study, did not feel that they would be distressed by discussing it. However the researcher will be aware that there is the possibility that others may become distressed by it or that in talking about this topic, other issues that distress the participant may arise. The researcher has extensive experience discussing diagnosis of dementia with people who are being given a new diagnosis, along with their carers, in her previous role as a consultant nurse. She also has experience in

discussing sensitive topics (such as end of life care) with carers of people with dementia from her previous clinical role and as such is very experienced in asking questions and guiding conversations in a manner that does not provoke distress and in interpreting both verbal and non-verbal signs of distress in others, responding appropriately with empathy and understanding and diffusing situations where necessary.

In the event that a participant becomes upset or distressed during the interview the researcher will support the person in an empathic and understanding way and allow them to express their emotions until they feel more at ease. The participant will be given the option to take a break or discontinue the interview. Haar et al (2014) suggest that we should trust the participant to choose whether they let go of their natural defence mechanisms and as researchers be responsive to individual situations, guided by bioethical principles and our own internal moral voice as a healthcare professional. If the person continues to appear upset or distressed after the interview has ended, then the researcher can refer the person back to the dementia and delirium team at Barts Health for community follow up to be arranged or offer information on how to access further support e.g. from their local Alzheimer's society, Dementia Care team or national dementia helplines.

In keeping with best practice the researcher will spend time towards the end of the interview talking about less emotional or intense topics, acknowledging the contribution the participant has made and engaging in social conversation to help the participant adjust from a research context back to their everyday life (Corbin & Morse 2003, Murphy et al 2015, McKillop & Wilkinson 2004). The researcher would not leave the person in distress and would offer to contact a friend or relative of the participant if they so wished. If the person with dementia had become distressed at any time then the researcher would contact that person's carer or next of kin to inform them, if they were not present. The researcher would also follow up with the participant and/or their carer a couple of days later to ensure the person has had no lasting distress.

It is essential that the interview process upholds the dignity of participants by ensuring they have as much control over the process as possible. This can be achieved in part by giving the participant the choice of time and venue for the interviews, allowing them to control the flow of the interview as far as possible, respecting their knowledge and experience and appreciating their contribution.

There is a concern that, in the analysis and reporting of in-depth interviews, the use of verbatim quotes to illustrate and justify findings or themes, may compromise external and internal confidentiality. External confidentiality refers to ensuring that participants cannot be identified from any published results or findings (Tolich 2004). In this study, at the point of transcribing the interviews, any potentially identifiable words or phrases will be replaced with pseudonyms. This will include removing all names from the transcript and replacing them with a pseudonym or a tag that typifies the person e.g. daughter, husband, friend, neighbour. Also any exact geographical locations which could be used to identify someone will be replaced with a meaningful descriptive term. This will be explained to participants at the time of informed consent.

Internal confidentiality refers to ensuring that participants in the same study are unable to identify each other based on published results or findings (Tolich 2004). This is of particular

concern in research where one participant may be closely connected to another participant in the study (e.g. carer and cared for person) and are being interviewed about the same event or experience. Other internal confidentiality issues could include one participant (e.g. the carer) asking the interviewer about the content of another participant's interview (e.g. the person with dementia), the interviewer using information from one participant (e.g. carer) to influence the content of the interview with another participant (e.g. person with dementia) and where participants may read or have access to each other's interview transcripts (Ummel & Achille, 2016).

This study will try to minimize the risk of breaching internal confidentiality in a number of ways.

To reduce the likelihood of one participant recognizing a quote from another participant they know when the findings are presented, data for the two groups – people with dementia and carers, will be analysed separately and reported separately. Consequently there will be a final set of superordinate themes for the group of people with dementia and a final set of superordinate themes for carers, with no cross referencing between individual people with dementia and their respective carers. The researcher will reflect on the quotes chosen to illustrate these themes and through a process of discussion with her academic supervisors, any quotes which appear sensitive or provocative and may increase the likelihood of recognition by another participant, will be removed from the findings and alternative quotes or ways to support the themes found.

If both the person with dementia and their carer are participating and in the course of an interview one participant asks if the other mentioned a particular topic for example, the researcher would take care to ensure that the information revealed in the other participant's interview remains confidential. In order to do this researcher must be aware of their nonverbal reactions as well as their verbal responses. As recommended by Ummel & Achille (2016), the researcher will be professional and friendly so as not to disturb the rapport they have with the participant and use this as an opportunity to remind the participant about the importance of protecting the confidentiality of all participants.

As the same researcher will be interviewing both people with dementia and carers, care will be taken to ensure that information provided by one participant is not used to influence questions or prompts in the interview with another participant, if they are part of the same caring relationship. As the focus of IPA research is in the meaning of the experience for the individual, then what is important to one participant may not be important to another. Through a process of reflexivity and discussion with her supervisors the researcher will ensure that each interview is treated as a separate entity.

Participants will be offered the opportunity to review the transcript of their interview before analysis takes place, so that they can see the anonymization process and also have the chance to remove anything that they had later regretted saying, again ensuring that control over the process lies with them. Participants will have the opportunity to decide how they would like to receive their transcript e.g. electronically, by post to home/ other address, to ensure they are comfortable that their transcript can be kept confidential if they so wish (Forbat & Henderson, 2005). The researcher will talk to the participant beforehand about keeping their transcript private and secure if the participant is concerned about other family members seeing what

they talked about and also about what to expect when seeing their own words on paper (Forbat & Henderson 2005). If they are particularly concerned about others seeing their transcript, the researcher can offer to bring a copy of the transcript to the second interview so the person can read it and the researcher take it away (Forbat & Henderson 2003). Arrangements could be made to do this after the second interview if it was practical. If participants wish to share their transcript with others they may do so. If the person with dementia wishes to see their transcript but is unable to read it for themselves, they will have the option of choosing another person to read their transcript to them. But if the researcher feels they do not have the capacity to make this decision or they do not wish anyone else to read their transcript, the researcher will offer to read the transcript to the person prior to the second interview.

Participants will be offered the opportunity to receive a summary of the findings at the end of the study. People with dementia will receive a summary of the findings from the interviews with people with dementia. Carers will receive a summary of the findings from the interviews with carers. These summaries will not include quotes, to reduce any possible anxiety participants may feel from seeing their own quotes on paper. However participants will be informed that anonymized quotes from their interviews may be used in the researcher's thesis and in subsequent publications.

8.1.3 Including people who lack capacity

The inclusion of people who lack capacity in research is important if we are to understand their diagnosis, treatment, care and needs (Dept. of Constitutional Affairs 2007) and to ensure they have the opportunity to participate in research if they wish to (Dobson, 2008). Sections 30 – 34 of the Mental Capacity Act (2005) outline the necessary requirements for including people who lack capacity in research. This study has been designed to ensure all these requirements are met.

The first requirement is that the project concerns the condition which impairs the capacity of the participant. This is a study to explore the timeliness of a dementia diagnosis received during a hospital admission and participants will include people who have received a diagnosis of dementia. Potential participants may lack capacity to consent as a result of their dementia which can impair memory, thinking, judgement and communication.

The second requirement is that the project could not be undertaken as effectively with the sole participation of people who have capacity to consent. We do not know if people who lack capacity to consent have different views to those of people with dementia who have capacity to consent, so by excluding them, any results from the study may misrepresent the views of this group of people. It is also possible that by excluding people who lack capacity to consent, the number of people able to participate in the study may be so small that it will be very difficult to generate any meaningful data and recommendations.

The third requirement is that the research must intend to provide knowledge of the causes, treatment or care of people affected by the same or similar impairing condition or that it concerns treatment or care of the condition. This study concerns the diagnosis of dementia and the decision making process to seek help for a diagnosis of dementia. Therefore all the participants will either have a diagnosis of dementia themselves or be the main carer for someone with dementia.

The fourth requirement is that the participant is likely to benefit from taking part in the research and that the benefit will not be disproportionate to any burden in taking part. The direct benefits to the participants in this study are likely to be small, but could include a sense of enjoyment and satisfaction in taking part in the interview, a sense of relief in expressing their feelings to someone is who ready to listen, a sense of empowerment and self-esteem in having their voice heard. If a participant expressed a wish for more support or information regarding their dementia, the researcher may also be able to put them into contact with services that could provide this. However the burden in taking part is also thought to be very small and the researcher aims to minimise any risk of distress in participating in an interview as outlined in the section on in-depth interviews above.

The fifth requirement is that if there are no benefits to the person and if the research concerns the gaining of knowledge about the condition, then there should be negligible risk to the participant and that the project should not interfere with the participant's freedom of action or privacy or be unduly invasive or restrictive. As described above the benefit to participants is likely to be very small but the risk is also thought to be negligible. The extent to which there is a benefit to a participant and the extent to which taking part represents a burden or risk is likely to vary between individuals. It will therefore be important to assess this on an individual basis in the process of consulting the person's carer as a consultee. The researcher will endeavour to understand whether the person who lacks capacity is usually happy to talk to others, particularly people they do not know and whether they are happy to talk about themselves, their feelings, their memory problems and their recent experiences. It will also be helpful to know how much the person understands about their diagnosis of dementia – what do they call it, do they ever refer to it or talk about it to family or friends. Understanding these things will help to determine whether benefit will outweigh risk or vice versa and hopefully also help the consultee in giving their opinion. As outlined previously the interview process has been designed so as to not restrict freedom of action and to uphold the privacy and dignity of participants and this will apply equally to those who lack capacity. In consulting carers of people with dementia at Waltham Forest Alzheimer's Society Dementia café, all the carers felt that the person they care for would enjoy taking part in an interview and although many would not have had capacity to consent, their carers felt the risks were minimal and would have been happy to give assent as consultees.

All efforts will be made to enhance the decisional capacity of potential participants. People with dementia will not be approached or contacted by the researcher unless they have expressed a willingness to participate in the study to their carer/ next of kin. Their carer/ next of kin will be encouraged to discuss the study with them and there is likely to be a minimum of two weeks between being first approached by the DAD team about the study and the first contact/ meeting with the researcher. Allowing sufficient time for them to consider their participation. In order to meet the needs of people who may find reading or concentrating on written information difficult, a brief information sheet providing only essential information about the study with pictures has been created, to be used with or without the full information sheet, depending on the needs of the participant. This was created using guidance from DEEP (2013) and was suggested by a carer during the study consultation and is recommended by the British Psychological Society (Dobson, 2008). When seeking the advice of the person's carer as

a consultee, the researcher will also seek advice on the best time of day to visit the person with dementia in order to assess their capacity to consent, as fatigue may affect their capacity to make decisions.

The researcher is very experienced in using the Mental Capacity Act (2005) and assessing capacity in people with all stages of dementia. In her previous role as nurse consultant for older people and dementia, she was frequently called upon to carry out complex capacity assessments in relation to alternative feeding, treatment decisions and discharge destination and care support decisions. In assessing the capacity to consent to participate in this study the researcher will also use guidance for researchers provided by the British Psychological Society (Dobson, 2008, p17) in the table below:

1**. Understand information – does the person understand what the research is about?**

- Does the person have a general understanding of the research project?
- Can the person indicate what is expected of them?
- Have attempts as described above to enable the participant to make decisions for himself not been successful?

2. Retain information – can the person hold the information in their mind long enough to use it to make a decision?

- Can the person recall information about the research?
- Having a poor memory *per se* is not sufficient grounds for saying that the participant cannot consent.

3. Use or weigh up the information

- Does the (prospective) participant consider the benefits and risks of taking part in the research?
- Can the person identify any consequences of participating or refusing to take part?

4. Communicate their decision

- Is the person unable to communicate their decision in any way, taking into account any specific language or communication difficulties?

If a potential participant is judged by the researcher to lack capacity then in accordance with the Mental Capacity Act (2005) a consultee will be sought. As people with dementia will only be eligible for the study if they have a main carer/ next of kin, they will be approached first to be a consultee where necessary. The process of assessing capacity and the possible need for a consultee will be discussed with the carer/ next of kin before the researcher meets with the person with dementia. This will allow them time to consider their possible role as a consultee and to consider what the wishes of the person with dementia might be, before they are required to make a decision. The aim of this will be to facilitate the assessment of capacity to consent and the subsequent research interview with the person with dementia to take place on the same day. If a consultee is required the carer/next of kin will be prepared for this and hopefully in a position to give their decision about being a consultee and the participation of the person with dementia. If the carer/ next of kin does not feel, for whatever reason they can act as a consultee, they will be asked if they can suggest an alternative friend/ family member who could be approached. If there is no one else who can act as a personal consultee, then a

nominated consultee would be approached for example the person's GP or a health care professional they are in regular contact with. However, it is envisaged that this is unlikely to be necessary.

8.2 Assessment and management of risk

This section will describe the risk management plan for dealing with any safeguarding issues that arise in the course of interviewing the participants. This will include any harm to participants or potential for harm to others.

The likelihood of safeguarding issues arising during the course of this study is low. However when talking about their pre diagnosis experience and their feelings about their diagnosis (or that of the person they care for) it is possible that participants may express feelings or disclose information that suggests that either the person with dementia or the carer is at risk. In these circumstances the researcher may have to break confidentiality in order to access the help the person may require. As part of the informed consent process the researcher will outline the circumstances in which confidentiality may be limited and the types of information that they would need to disclose and to whom. In line with the British Psychological Society Code of Ethics (2009), breaches of confidence should be limited to exceptional circumstances where there appears to be sufficient evidence to raise serious concern about the safety of clients, the safety of other persons who may be endangered by the client's behavior or the health, welfare or safety of children or vulnerable adults. In the event that a breach of confidentiality is required, the researcher will follow the Barts Health safeguarding policy, with the support of the Barts Health safeguarding team and the Barts Health DAD teams.

8.2.1 Risk management plan for dealing with any potential risk/harm to the participant

If a participant who had the capacity to give informed consent disclosed information that suggested they were at risk of harming themselves, the researcher would express concern about their disclosure and ask whether they had talked to anyone else/ sought support for how they are feeling. They would encourage the person to seek support or talk to significant others about how they feel and offer to pass on information to the DAD team at Barts Health who could make an appropriate referral for them e.g. to the community mental health team, dementia care team, Alzheimer's society etc. The researcher would also leave with the person, pre-prepared information about sources of support and contact details for CMHT/ dementia care team/ Alzheimer's Society/ social services/ National dementia helplines. If the person was distressed, the researcher would offer to contact a friend/ family member as appropriate.

If a participant who had lacked the capacity to give informed consent disclosed information that suggested they were at risk of harming themselves, the researcher would, as before, express concern about their disclosure and ask whether they had talked to anyone else/ sought support for how they are feeling. They would encourage the person to seek support or talk to significant others about how they feel and offer to pass on information to the DAD team at Barts Health who could make an appropriate referral for them e.g. to the community mental health team, dementia care team, Alzheimer's society etc. In addition to this they would discuss the concern with the person's consultee/ carer, offer to contact the DAD team on their behalf and leave pre-prepared information about sources of support and contact

details for CMHT/ dementia care team/ Alzheimer's Society/ social services/ National dementia helplines.

The researcher would discuss the disclosure with her academic supervisors, who are both clinically qualified (Prof. Meyer is a registered nurse, Prof. Oliver is a medical consultant) and if further advice was needed, the safeguarding team at Barts Health are happy to discuss any concerns and offer advice about whether a referral is required.

If the researcher felt there was an immediate, serious concern, they would discuss the situation with the safeguarding and/ or DAD team to ensure an immediate referral for support was made.

8.2.2 Risk management plan for dealing with safeguarding issues for potential harm to others

If any participant disclosed information that suggested they were at risk of harming others (either an individual or a wider public risk), the researcher would express concern about their disclosure and ask whether they had talked to anyone else/ sought support for how they are feeling and encourage the person to seek support or talk to significant others about how they feel. In line with the Barts Health safeguarding policy the researcher would explain that they had a duty to protect the person(s) at risk of harm and that they would need to discuss the disclosure with the safeguarding team/ DAD team to decide if a referral needs to be made on their behalf e.g. to the community mental health team/ dementia care team/ social services/ police. The researcher would explain to the participant that they would be kept informed of any referrals made on their behalf.

8.2.3 Risks to the researcher

The only potential risk to the researcher is that of personal safety when visiting participants in their own homes. The researcher plans to follow the advice and guidance provided by The Suzy Lamplugh Trust (2014) on Keeping Safe - Making a home visit and the Code of Practice for the Safety of Social Researchers (Social Research Association). In accordance with this advice, where interviews are taking place in office hours, the department administrator will know the date, time and address of the interview and out of office hours the researcher will ensure her supervisor is aware of the date, time and address of interviews taking place. Neither the administrator nor the supervisor will be able to make connections between the interview timings and settings and the data produced by the interviews.

8.3 Research Ethics Committee (REC) review & reports

Before the start of the study, approval will be sought from a REC via the HRA approval process for the study protocol, informed consent forms, participant information sheets, consultee information and assent forms and the interview schedules.

Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study.

All correspondence with the REC will be retained. It is the Chief Investigator's responsibility to produce the annual reports as required. The Chief Investigator will notify the REC of the end of the study.

8.4 Peer review

The protocol for this study has been subject to a peer review by three experts. Following the peer review of two leading dementia research professors – Professor Wendy Moyle and Professor Tom Dening, minor amendments were made to the protocol to improve the wording and clarity of a number of the points made. These included:

- A short summary in everyday English added to the start of the protocol
- Making clear that it is not necessary to have both the carer and the person with dementia participating – including changing the wording of the title from "people with dementia and their carers" to "people with dementia and carers of people with dementia"
- Justification for not routinely informing a participant's GP

Following the peer review of Professor Jonathan Smith, who developed Interpretative Phenomenological Analysis further amendments were made which include:

- Increase in sample size from 3-6 people with dementia and 3-6 carers to 5-6 people with dementia and 5-6 carers.
- Clarity that dyadic analysis will not be undertaken to reduce the liklihood of breaching internal confidentiality
- Improved wording of interview schedules

8.5 Patient & Public Involvement

People with dementia and their carers attending the Waltham Forest Alzheimer's Society Dementia café were consulted on the acceptability and design of the study, along with reviewing study documentation such as information sheets and interview guides. They were also invaluable in giving their advice and opinions on taking part in research studies and what they would find most helpful if they were being interviewed as part of a research study.

The people with dementia and carers consulted all felt that the topic of the study was acceptable and that the questions proposed in the interview guides were not too sensitive or intrusive. Both people with dementia and their carers preferred short questions. People with dementia who had been involved in research involving interviews or questionnaires previously felt that being able to answer in their own words was easier that choosing an answer from a pre-determined list. Although some of the people with dementia consulted would be unlikely to have capacity to give fully informed consent, their carers would have been happy to act as consultees and give assent for them to take part. Many of the carers felt that the person they cared for would enjoy talking to someone and find taking part in an interview stimulating.

Many of the people with dementia consulted were either unable to read and understand the whole participant information leaflet or felt they would not have the concentration to read the whole leaflet. It was the suggestion of a carer, to create a one page information sheet of simple statements about the study which could then be supplemented by either reading the whole information sheet if they wished or by the additional information being verbally explained by the researcher and carer. As a result, an additional brief participant information sheet for people with dementia was created.

Some people expressed a preference for where they would like to be interviewed, suggesting being interviewed whilst they were attending something like the dementia café. Others expressed concern about a stranger coming to their house. For these reasons all efforts will be made to accommodate participants to be interviewed where they choose e.g. identifying a private, quiet room at day centres/ other venues that could be used for an interview. In addition, where appropriate and if time allows, the researcher will try to meet the person with dementia and their carer before they are discharged from hospital to provide some reassurance to the person when they are visited at home.

In addition to consulting people with dementia and their carers, stakeholders at Barts Health, who will be acting as a participant identification centre, have also been consulted. The lead nurse for dementia and clinical nurse specialists in the Dementia and Delirium teams have been consulted on the appropriateness of the methods for approaching and recruiting participants and consultant psychiatrists and consultant geriatricians working in the memory and liaison services have been consulted on the appropriateness of the study topic and research questions. Their input has been invaluable in helping to design the study and make relevant contacts within Barts Health and the local community.

8.6 Regulatory Compliance

Barts Health NHS Trust will act as the sole participant identification centre for the study. Permission has been sought from the Trust Research and Development department and following HRA approval all relevant documentation will be forwarded to the R&D department.

For any amendment that will potentially affect the NHS permission, the Chief Investigator will confirm with Barts Health R&D department that NHS permission is ongoing.

8.7 Protocol compliance

The likelihood of protocol deviations, non-compliances, or breaches from the approved protocol for this study are very low as the chief investigator will be carrying out the research themselves. The only aspect of the study being managed by others is the identification of potential participants.

Accidental protocol deviations can happen at any time. In the event of any protocol deviations, these will be recorded and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Any protocol deviations will be discussed in educational supervision monthly or in between times if there is an immediate concern.

8.8 Data protection and patient confidentiality

The first part of this section details how participant confidentiality will be maintained and how the study is compliant with the seven principles of the Data Protection Act (1998). The second part shows a flow chart depicting how the data will be handled and stored at each stage of the study.

Responsibility for the accuracy, completeness and security of research evidence during the study will lie with the chief investigator. Management of the data will be reviewed on a monthly basis as part of the CI's educational supervision. She will also ensure that the nurses in the Dementia and Delirium teams, who will be identifying potential participants and approaching them about the

study have been trained on their role in managing personal data and complying with the Data Protection Act. As registered nurses this is something they are required to do as part of their clinical role, but their responsibilities in terms of managing personal data for research will be explained.

8.8.1. Principles of the Data Protection Act

The first principle of fair and lawful processing requires that a research subject is informed of the identity of the data controller and any nominated representative and the purposes for which the personal data is to be processed. The data controller for this study will be City University London. Participants will be informed that their personal data, in the form of name, address and contact details, will only be used for the purpose of contacting them to arrange interviews and sending them copies of transcripts/ result summaries by post. All data collected will be anonymised to ensure identifying features are removed.

The second principle states that personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or purposes and the third principle states that personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed. As described above only personal data in the form of contact details will be collected and used for the purpose of contacting the participant. The anonymised data collected will only be used for the purpose of the Chief Investigator's PhD study and any subsequent publications or conference presentations.

The fourth principle states that personal data shall be accurate and, where necessary, kept up to date. The Chief investigator will take responsibility for ensuring that personal data used to contact participants in this study is accurate and kept up to date.

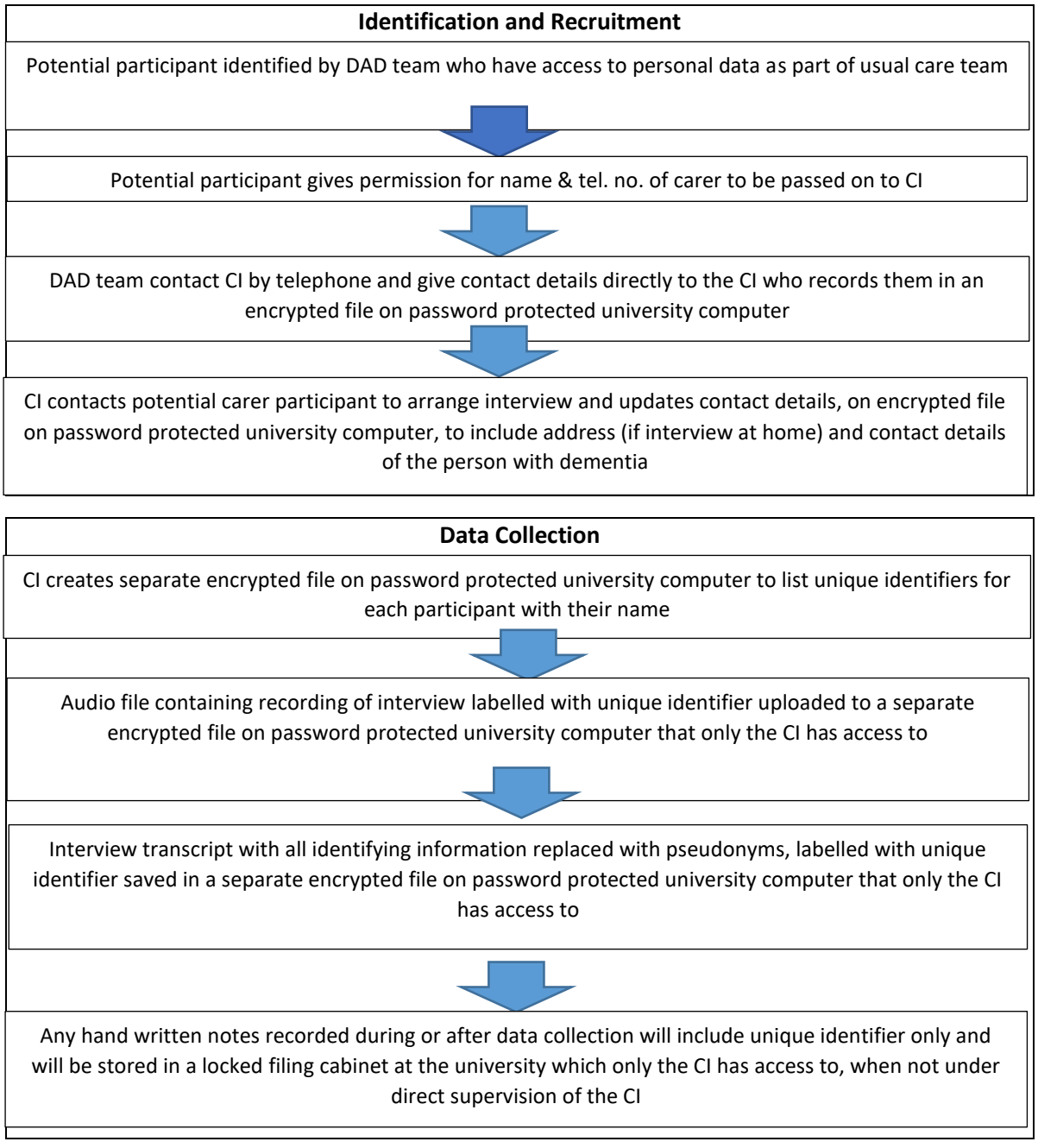
The fifth principle states that personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or purposes. The personal data used to contact participants will be kept until the end of the study in order for summaries of the research findings to be sent to the participant if they wish. Once this has been done the personal contact details of the participants will be destroyed. The anonymised data collected will be kept for 10 years as required by City University.

The sixth principle gives an individual the right to be informed by someone using personal data about him or her. As described previously only the chief investigator will use the personal data collected to contact the participants. All other data collected will be anonymised to remove any identifying features.

The seventh principle states that security must be appropriate to the nature of the data to be protected. The chief investigator will be responsible for the overall data security. Personal contact details will be stored in an encrypted file on a password protected university computer that only the chief investigator has access to. Audio files of interviews and anonymised transcripts of interviews will be stored in separate encrypted files on a password protected university computer that only the chief investigator has access to. They will be stored on a networked drive which will ensure that data is backed up regularly and stored securely minimizing the risk of loss, theft or unauthorized use. Any hand written notes and consent forms will be stored separately in a locked filing cabinet that only the chief investigator has access to, when not under the direct supervision of the chief investigator. Only members of the chief investigator's educational supervision team will see notes made and interview

transcripts in whole, but these will be anonymised and be reviewed in the presence of the chief investigator.
The eighth principle states that personal data should not be transferred outside of the European Economic Area. Only the CI will have access to the personal data of participants and any subsequent publications or conference presentations will only contain anonymised data.

8.8.2 Data management throughout the study



Data Analysis

Initial stages of hand written analysis of interview transcripts will be stored in a locked filing cabinet at the university which only the CI has access to, when not under direct supervision of the CI

Tables of emerging themes and findings will include direct quotes from interviews which will be anonymised and these will be stored in a separate encrypted file on a password protected university computer that only the CI has access to

Dissemination of findings

Findings of the study will be written up as part of the CI's PhD thesis. This will include direct quotes from interviews and reflections on the data collection process. No identifying data will be included, quotes will be anonymised and pseudonyms used to replace any identifying data. The thesis will be stored on a password protected university computer but paper copies will be shared with examiners and the final thesis may be published via an open access publisher.

Summaries of the findings will be compiled for participants, if they have previously expressed a wish to receive them. The summary of findings for participants will not include direct quotes from interviews and care will be taken to ensure there is no identifying data within the summary.

Data storage after completion of the study

Following completion of the study the personal contact details of participants will be destroyed

All other electronic data from the study will be stored in the original encrypted files on a password protected university computer and hand written notes in a locked filing cabinet at the university, which only the CI has access to, for 10 years as per City University guidelines. Access to the files will only be granted under supervision of the CI for audit purposes.

Findings will be disseminated through peer reviewed publications and conferences. These may include direct quotes from interviews and reflections on the data collection process. No identifying data will be included, quotes will be anonymised and pseudonyms used to replace any identifying data.

8.9 Indemnity

Arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research - City University has Professional Indemnity and Clinical Trials insurance cover for its liability relating to all of these activities. Professional Indemnity - £15 million in any one occurrence and insured with Zurich. Clinical Trials - £10 million in any one occurrence and insured through Arthur J. Gallagher

Arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research - City University has Professional Indemnity and Clinical Trials insurance cover for its liability relating to all of these activities. Professional Indemnity - £15 million in any one occurrence and insured with Zurich. Clinical Trials - £10 million in any one occurrence and insured through Arthur J. Gallagher

Arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research - City University has Professional Indemnity and Clinical Trials insurance cover for its liability relating to all of these activities. Professional Indemnity - £15 million in any one occurrence and insured with Zurich.

As required by City University the following statement will appear at the end of the participant information leaflets:

City University London holds insurance policies which apply to this study. If you feel you have been harmed or injured by taking part in this study you may be eligible to claim compensation. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action.

8.10 Amendments

This section describes the process for dealing with amendments to the study protocol or documentation.

- The need for any amendments will be discussed at the chief investigator's monthly supervision with her academic supervisors.
- HRA guidance will be used to determine if the amendment is substantial or non-substantial and the final decision will lie with the chief investigator's academic supervisor.
- As per HRA guidance both substantial and non-substantial amendments will be notified to the relevant bodies:
    - Substantial amendments will be notified via the amendment form in IRAS and emailed with accompanying documents to the REC. The outcome of this process will be communicated to Barts Health R&D and the DAD team by the chief investigator.
    - Non-substantial/ minor amendments will be submitted to HRA amendments using the non-substantial amendments form and the outcome of this process

will be communicated to Barts Health R&D and the DAD team by the chief investigator.

- The chief investigator will be responsible for ensuring there is a clear audit trail identifying the most recent protocol version.

8.11 Access to the final study dataset

This section will describe who will access to the final dataset.

The chief investigator is the only person who will have full access to the final dataset. She will share sections of the data e.g. interview transcripts, tables of emerging themes, draft chapters of results and discussion with her academic supervisors as required.

9. DISSEMINATION POLICY

9.1 Dissemination policy

This section will describe the dissemination policy for the study.

The data arising from the study will owned by the sponsor City University London. The data will be analysed as described previously and will be reported as part of the chief investigator's PhD thesis. Once her PhD has been successfully completed the full thesis may be accessed by staff or students at City University in hard copy via City University library. It will also be made publically available electronically by being placed on City Research Online, the open access institutional repository of City University London.

A summary of findings will made available to participants at the end of the study. This will be sent to them in the format of their choice, if requested. A summary of the findings will also be made available and presented to the Dementia and Delirium teams at Barts Health NHS Trust. The chief investigator will also consult with local Alzheimer's Society branches to determine the best way to present the findings to the wider community e.g. via their newsletter or in person at dementia café events.

The chief investigator may submit peer reviewed publications arising from the study and/or present the findings at appropriate conferences. She will aim to complete these within three years of successful completion of her PhD.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final study report will be granted to the chief investigator as it will form part of her PhD thesis. Publications arising from the study may be written in conjunction with the chief investigators academic supervisors.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

The following is the list of documentation required by Barts Health R&D department once HRA approval has been obtained:

1) **Costing:** Declaration of No cost form - to confirm if there is no cost associated with the study which will be incurred by Barts Health NHS Trust
2) **Contract:** For access permissions the study team member working at Barts Health NHS Trust must have a substantive/honorary contract with BHT – all members of the DAD teams who will be identifying and approaching patients have substantive contracts with Barts Health.
3) **Research Protocol**: Please provide the research protocol /research proposal.
4) **IRAS:** Please complete the online IRAS form.
5) **Participant Documents:** You will need to provide the Participant Information Sheet, Consent, questionnaire etc.
1) **Scientific Peer Review:** You will need to provide an evidence that your study has been peer reviewed and you may do this by completing the statement below. This must be 'qualified peer' or your educational supervisor with expertise in the subject area of work, independent (i.e. not involved in the study. There is no requirement for the reviewer to be internal/ external/ known/ not known to the researcher:
   'I confirm that I have read and understood <protocol XXX (title, version, date)> and feel that the project objectives are clear, that the project has merit in its rationale and methodology, and is of value'.
   Print Name:
   Signature:
   Job Title:
   Date:
1) Departmental Approval: Please complete the below statement, this person need to be independent from the study and hold a senior position at the department where you will be conducting the study (in your case where patients will be Identified)
   'I confirm that project XXX <protocol XXX (title, version, date)> can be undertaken by the XXX department and can be accommodated in terms of space, resource and facilities and that the department can see no reputational risk for this project being undertaken by the dept'.
   Print Name:
   Signature:
   Job Title:
   Date:
6) **Sponsorship Letter**: You will need to provide a letter of sponsorship from City University stating that they are supportive of the study.
7) **Insurance & Indemnity:** This is usually accompanied with the sponsorship letter.

8) **CV:** You will need to provide a brief CV of yourself and your educational supervisor.
9) **GCP/RGF certificate:** You will need to provide the evidence (certificate) of training.

11.2 Appendix 2 – Schedule of Procedures

Procedures/ Person carrying out procedure and venue	**DAD team in hospital**	**Researcher in hospital/ telephone**	**Researcher at venue of participant choice**
Approach and introduction to study - Carer	1		
Approach and introduction to study – Person with Dementia	1		
Further discussion re: participation		1 x prior to 1st interview 1 x prior to 2nd interview	
Capacity assessment (for people with dementia) and Informed consent			1 x prior to 1st interview 1 x prior to 2nd interview
Interview with person with dementia			1st interview as soon as possible after agreement to participate 2nd interview 3-6 months later
Interview with carer			1st interview as soon as possible after agreement to participate 2nd interview 3-6 months later

11.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**
1.	V 0.1		M Parker	Changes made following peer review as detailed in section 8.4

11.4 Appendix 4: The Bradford Wellbeing Profile Positive and Negative Behavioural Indicators

Positive behavioural indicators

1. Can communicate wants, need and choices. The person can communicate what they want or need, verbally or non-verbally. They can use words or gestures (or both) to get across what they want or do not want. They can challenge someone who is trying to get them to do something they do not want to do. Aggression provoked by the experience of receiving care (e.g. being told what to do or by feeling frustrated and powerless) can be seen as a sign of being able to communicate wants, needs and choices. (However see also 'anger and aggression' under ill-being.) Silence or inactivity can communicate reluctance, fear, pain, disapproval, confusion etc.

2. Makes contact with other people. The person attempts to make contact with other people, for example by talking, making sounds, waving, touching, using gestures, making eye contact, winking, leaning forwards, holding hand out. It is not necessary to be able to talk to make contact with others. The person is able to initiate contact as well as respond to others.

3. Shows warmth or affection. The person shows signs of warmth or affection towards other people, and is responsive when others are warm or affectionate with them. Warmth or affection can be directed at visitors, caregivers, animals, dolls or people not actually present such as a dead spouse or absent family members. Words of endearment such as 'like', 'love', words of positive regard such as 'nice', and 'pretty', 'lovely', 'good', 'great' and words of gratitude such as 'thank you' are signs of warmth. Also look out for sounds (e.g. cooing and chuckling) and gestures (e.g. holding hands, hugging, stroking, patting, smiling, gazing, kissing, blowing kisses and holding). Also be on the lookout for 'a fond look in the eyes', looking bright eyed or animated when a person is present; tracking a person's movements with the eyes; disguised or 'rough' affection shown by gestures like slapping someone on the back.

4. Shows pleasure or enjoyment. The person shows signs of pleasure, enjoyment or happiness in the course of ordinary everyday life, for example in response to food and drink, social contact and the sights, sounds and smells of the world around them. Examples: enjoying a good meal, giving a contented sigh when tucked into bed, looking bright-eyed and alert when an entertainer is performing, looking relaxed and dreamy during a hand massage, smiling at a visitor.

5. Alertness, responsiveness. The person responds to their surroundings. They react to an
unexpected noise or movement, or can be seen to be watching things that are happening. Different people will be alert to different things e.g. watching other people, looking birds or plants outside the window, noticing features of the building, looking at TV, listening to music. Careful observation is needed to distinguish between vacant stating and someone who is watching the movement of leaves on a tree, or particles of dust in a sunbeam. People with severe dementia may only be responsive to things in their immediate vicinity***.***

6. Uses remaining abilities. Given appropriate stimulus and encouragement, a person responds to their environment making use of retained abilities. Examples: a person who is able to speak uses speech when spoken to, someone who can walk will walk, and someone who can sing will join in when others are singing a favourite song.

7. Creative expression. There is scope for creative expression in many activities, but not all
activity is creative. When a person is putting something of him/herself into whatever they are doing, rather than doing it in a 'let's get this over and done with' manner, it will count as creative expression. In particular, music, dancing, visual arts provide opportunities for creative expression.

8. Co-operative or helpful. The person volunteers help, is willing to help when asked or cooperates when others are helping them. What is important here is willingness to help or cooperate, rather than outcomes. Some attempts to help may not actually be helpful, but the attempt or intention to help or be co-operative is what counts.

9. Responding appropriately to people/situations. The person shows awareness of other
people's needs or feelings. Examples: moving out of the way to let another person past, giving a hand to someone who needs support, showing concern for someone who is distressed.
10. Expresses appropriate emotions. The person shows emotion in line with their personality. Examples: sadness when a visitor leaves; tears when remembering that someone they cared for is dead; elation after an argument; anger when someone treats them badly; frustration when they try to do something and can't; irritation when others are annoying; boredom when there is nothing to do.
11. Relaxed posture or body language. The person has times when they are both alert and relaxed, with a calm facial expression and without repetitive movements. Times of blank
withdrawal, when alertness is lost, do not count.
12. Sense of humour. The person expresses a sense of humour, with jokes, comments or
actions, or responds to the humorous comments or actions of others with smiles or laughter. This can include laughter when something goes wrong – e.g. a caregiver drops a box of dominoes.
13. Sense of purpose. The person shows that they feel able to make things happen, or have something to contribute. They undertake real or pretend work. Examples: making the movements of cleaning; carrying a bag with a purposeful expression; rummaging in a cupboard; removing cups from the table; helping someone out of a chair.
14. Signs of self-respect. The person shows signs of trying to preserve dignity, modesty or self-respect. Examples: Adjusting clothing, taking pleasure in grooming, wiping up spilt food, not wanting to participate in a game because they think it is childish. Resisting help with private matters like toileting; refusing to co-operate when treated in a bossy or patronising manner or reacting angrily to other personal detractions can count as self-respect.

Negative behavioural indicators

1. Pain, physical discomfort. The person reports pain or discomfort, or there are non-verbal signs such as fidgeting, grimacing, wincing, sighing, holding or rubbing. Pain may be linked to other negative signs such as aggression, anxiety and agitation. It is important to remember that physical discomfort, stiffness and pain are all common in older people. Not being in constant pain is not a reason to dismiss pain as unimportant.
2. Tense body. Tight muscles in face or any other part of the body.
3. Agitation, restlessness. The person moves a lot, and in a manner which suggests that they are upset, anxious or uncomfortable rather than purposeful**.**
4. Anxiety, fear. The person reveals anxiety or fear in what they say, their facial expressions, other body language and behaviour. There are a range of instinctive responses to fear which include aggression (fight), running away (flight), staying very still (freeze) and seeking safety in numbers (flock). Also, the attachment system may be activated, in which case the person will seek out an attachment figure to protect them and reassure them. In childhood this is typically mother, and the need to find mother (or father) when alarmed often resurfaces in people with dementia.

5. Anger, frustration. The person expresses a great deal of anger and frustration. Anger erupts without warning and is persistent. Their anger is very easily triggered and is not necessarily a reaction to what is happening (e.g. resisting personal care) or what the person believes is happening (e.g. believing that someone is attacking them.)
6. Depression, despair. The person shows several signs of depression such as low mood, lack of interest in usual activities, being unresponsive to pleasant events, being irritable, having multiple physical complaints, loss of appetite, difficulty falling asleep, early waking, disturbed sleep, suicidal thoughts, pessimism, poor self-esteem, negative outlook, symptoms worse in the morning.
7. Sadness, grief. The person is persistently sad and grieving.
8. Listlessness, withdrawn. The person is frequently unresponsive, and seems to be blank and withdrawn. There are no signs that they are day-dreaming, or occupied in their own mind. Even when given long periods of sustained attention (e.g. 15 minutes) they do not respond.
9. Boredom. The person indicates verbally or non-verbally that they are bored.

Appendix 18 Phase 2 - Research Ethics Committee Approval

NHS
Health Research Authority

London - Camberwell St Giles Research Ethics Committee

Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 02071048044

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

16 January 2017

[redacted]

Dear Ms Parker

Study title:	**The timeliness of receiving a dementia diagnosis during an acute hospital admission: exploring the perceptions of people with dementia and their carers.**
REC reference:	**16/LO/1925**
Protocol number:	**N/A**
IRAS project ID:	**208826**

Thank you for your letter of 06 January 2017, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair, the Alternate Vice Chair Ms Bostock and Committee member, Dr Bajo.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone

publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]	Version 1	05 October 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Letter from sponsor and evidence of indemnity]	Version 1	24 June 2016
GP/consultant information sheets or letters [Letter to GP re: info/ support]	Version 1	28 September 2016
Interview schedules or topic guides for participants [Interview guide for carers interview 1]	Version 2	26 September 2016
Interview schedules or topic guides for participants [Interview guide for carers interview 2]	Version 2	26 September 2016
Interview schedules or topic guides for participants [Interview guide for people with dementia interview 1]	Version 2	26 September 2016

Interview schedules or topic guides for participants [Interview guide for people with dementia interview 2]	Version 2	26 September 2016
IRAS Application Form [IRAS_Form_07102016]		07 October 2016
IRAS Checklist XML [Checklist_05012017]		05 January 2017
Letter from sponsor [Letter from Sponsor and evidence of indemnity]	Version 1	24 June 2016
Letters of invitation to participant [Letter of invitation to participant]	Version 1	28 September 2016
Letters of invitation to participant [Letter of invitation to consultee]	Version 1	28 September 2016
Other [Good Clinical Practice in Research (secondary care) Certificate of Completion]		07 September 2016
Other [GCP Informed Consent with Adults Lacking Capacity Certificate of Completion]		07 September 2016
Other [REC Provisional opinion request for further information reply letter]	Version 1	05 January 2017
Participant consent form [Consent form]	Version 1	28 September 2016
Participant consent form [Consultee Declaration Form]	Version 1	28 September 2016
Participant information sheet (PIS) [Person with Dementia Easy Read]	Version 1	28 September 2016
Participant information sheet (PIS) [Consultee Information Sheet]	Version 1	28 September 2016
Participant information sheet (PIS) [Person with dementia information sheet version 2]	Version 2	29 December 2016
Participant information sheet (PIS) [Carer information sheet version 2]	Version 2	29 December 2016
Referee's report or other scientific critique report [Protocol peer review report]	Version 1	28 September 2016
Referee's report or other scientific critique report [Supervisor ethical review form]	Version 1	05 October 2016
Research protocol or project proposal [Study Protocol]	Version 1	05 October 2016
Summary CV for Chief Investigator (CI) [CV]	Version 1	
Summary CV for supervisor (student research) [Supervisor summary CV]	Version 1	
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Lay summary and flow chart of protocol]	Version 1	28 September 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators

- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/1925	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Mr John Richardson Chair

Email:nrescommittee.london-camberwellstgiles@nhs.net

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Alison Welton*

Ms Katherine Ouseley, Joint Research Management Office (JRMO)

Appendix 19 Phase 3 - Research protocol for Quantitative Study

Study Protocol

What are the characteristics of people referred to a memory clinic via their GP and via the acute hospital?

Chief Investigator/ PhD student: Michelle Parker, City, University of London, Northampton Square, London EC1V 0HB, [redacted]

Supervisors: Professor Leanne Aitken, City, University of London, Northampton Square, London EC1V 0HB Tel. [redacted]

Dr Sally Barlow, University of London, Northampton Square, London EC1V 0HB. Tel [redacted]

Dr Juanita Hoe, University of London, Northampton Square, London EC1V 0HB. [redacted]

Protocol Version no: 1.2

Protocol date: 19/9/18

Introduction

Dementia is a progressive neurocognitive syndrome characterised by deterioration in memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgement (WHO 2017). It is estimated that 850,000 people are living with dementia in the UK and predicted that globally this will increase by over 200% by 2050 (Prince et al 2014). The annual cost of dementia to the UK economy is £26bn and is expected to double in the next 25 years, with a higher cost to health and social care than cancer and chronic heart disease combined (Prince et al 2014).

Of the estimated 850,000 people in the UK living with dementia only 539,062 people have a formal dementia diagnosis (Alzheimer's Research UK 2018). Improving awareness and early diagnosis has been a key priority in dementia policies worldwide, including the UK (Rosow et al 2011). The proposed benefits to a diagnosis made early in the disease process include the ability to plan for the future and access services (Dementia Action Alliance 2013), prescription of medication which may slow progression of symptoms and education for carers and those with dementia about what to expect (Leifer 2003). There is also a likely economic argument in favour of early diagnosis (Prince et al 2011). However it is recognised that these arguments are not always supported by research and further study of evidence based interventions to improve symptoms and quality of life and observational studies on the outcomes of early diagnosis are needed (Prince et al 2011). In England the introduction of financial incentives in primary and secondary care have sought to encourage health professionals to identify and diagnose dementia. Further, public awareness campaigns have sought to encourage people to seek help if they or someone they cared for had concerns about their memory. Despite a 56% rise in the number of people receiving a diagnosis between 2010 and 2016, there remain a significant proportion of people without a formal diagnosis (Alzheimer's Research UK 2018). Interventions aimed at improving awareness of signs and symptoms amongst the general public and addressing factors associated with identification and diagnosis in primary health care have been the focus of some research in recent years e.g. Livingston et al (2017), Chan et al (2010), Downs et al (2006), Iliffe et al (2015). However, a review by Mukadam et al (2015) found limited evidence of successful interventions to increase diagnosis rates, however this may be partly due to a lack of sufficient evidence.

In the case of a dementia diagnosis the most common help seeking pathway is via primary care services, often with a carer of a person with symptoms seeking help on their behalf via a GP. In England government incentives to increase diagnosis rates have focused beyond primary care to secondary care settings. The acute hospital admission is seen as an opportune time to recognise undiagnosed dementia in a population who have not sought help in primary care (Russ et al 2012). The aim is to ensure people are diagnosed or followed up for diagnosis appropriately in an attempt to reduce the diagnosis gap (Sampson et al 2009). To date research on this population has been limited to prevalence studies, which in the UK and Ireland suggest undiagnosed dementia can be present in up to 50% of people identified to have a cognitive impairment on admission to hospital (Sampson et al 2009, Meagher et al 2014, Jackson et al 2016). This group of people have been identified as older and frailer than those with a recognised dementia on admission (Jackson et al 2016).
Previous reviews of the dementia diagnosis pathway and help seeking in dementia reveal a complex process of decision making that requires further research into the interpersonal factors involved (Werner et al 2014, Perry-Young et al 2016, Mukadam et al 2011, Bunn et al

2012). The studies in these reviews are largely based on community populations, who have reached the point of seeking help for a diagnosis and are easily accessible by researchers. Less is known about the oldest old, those who do not access services or those with comorbid health conditions (Bunn et al 2012). All of which are characteristics identified in the group of people with undiagnosed dementia presenting to the acute hospital (Jackson et al 2016). A recent recommendation of a UK taskforce on dementia research priorities (Alzheimer's Society 2018) was to understand why people may voluntarily not wish to receive a dementia diagnosis and the consequences and unmet need for support that may result. To do this there is a need to identify and understand the experiences of people who do not seek help for a dementia diagnosis. People identified as having probable dementia at the time of an acute hospital admission are therefore a population of interest. Previous studies have not sought to identify any differences between people with undiagnosed dementia presenting at acute hospitals and those seeking help for a diagnosis via their primary care health provider. There is a need to obtain data on both groups – those actively seeking help and those not – to understand whether differences exist and to understand in more detail why the group of people diagnosed as a result of an acute hospital admission have not previously sought help.

Preliminary analysis

As part of a service evaluation in 2015, an analysis of the first 208 referrals to the Newham University Hospital memory clinic between January 2013 and June 2013 was conducted. This revealed a number of significant differences between those referred by their GP to the memory clinic and those referred by the acute hospital and other sources.

Of interest the group referred by the acute hospital were significantly older (mean 80.5 yrs) than those referred by their GP (mean 73.6yrs) (p=0.000). They also had significantly more hospital admissions (p= 0.000), with 43.9% of the hospital group having had 1 or more admissions in the 12 months prior to referral compared to 19.6% of the GP group. There was also a significant difference in mortality (p=0.000) with 99.1% of the GP group alive at 6 months post referral compared to 76.8% of the acute hospital group and 98.2% of the GP group still alive at 12 months post referral compared to 74.4% of the hospital group (p=0.000).

An analysis of those receiving a dementia diagnosis following referral also showed significant differences in age, with those referred by the hospital and other sources having a mean age of 83.2yrs compared to 78.5yrs in the GP group (p=0.023). There was also a significant difference in the number of hospital admissions in the 12 months prior to referral (p=0.002), with 17% of the GP referral group having had 1 or more admissions compared to 54.5% of the hospital referral group. Significant differences in mortality also remained in the group diagnosed with dementia (p=0.014) with 100% of the GP group alive at 6 months post referral compared to 87.8% of the group referred by the acute hospital and other sources and at 12 months post referral 100% of the GP group still alive compared to 82.9% of the hospital and others referral group (p= 0.003). In addition, those referred by the hospital were significantly more likely to have greater cognitive impairment at the time of their diagnosis (p=0.002), with 93.9% diagnosed as having moderate or severe impairment compared to 57.4% of the GP referral group.

Further analysis on a larger sample of referrals, to include additional variables associated with past medical history would be beneficial to gain greater insight into the characteristics of

people referred and diagnosed with dementia during or following an acute hospital admission. This will enable the subsequent qualitative phase of the study to explore any differences identified in more detail with carers of people referred via the acute hospital, to identify ways in which people could be supported to seek help earlier or supported in their decision making process to seek help.

Overall Study Aim

This quantitative study is part of a larger PhD study which aims to identify and understand the characteristics and experiences of people who receive a dementia diagnosis during or as a result of an acute hospital admission.

Objectives and research questions

The objective in this phase of the study is to identify the demographic and clinical characteristics of people referred to the memory clinic via different referral sources.

The quantitative research questions are based around a comparison of referral source:

- What are the characteristics (e.g. age, gender, ethnicity) of people referred to the memory clinic via different referral sources?
- How many people referred to the clinic receive a diagnosis of dementia and does this differ between referral source and other characteristics?
    - What sub-type and severity of dementia are people diagnosed with and does this differ between referral source and other characteristics?
- Do the number of co-morbidities differ between referral source and other characteristics?
- Do the number of hospital admissions in the 12 months prior to referral differ between referral source and other characteristics?
- What proportion of people are still alive six months and 12 months post referral and does this differ between referral source and other characteristics?
- What are the factors associated with diagnosis of dementia?
- What are the factors associated with death from any cause?

Method

This phase of the study will involve analysis of anonymised data extracted from the Newham memory clinic database and the corresponding electronic patient records.

Setting and Participants

Between 2013 – 2016 the memory clinic in Newham was based at Newham University Hospital and all people requiring memory assessment within the London Borough of Newham were referred to this one central clinic. Referrals were received from GP's, the acute hospital and other community teams. Data collected as part of the referral and assessment process were recorded in a database held by the lead consultant for the clinic and additional information was collected and recorded in the patient's electronic record as part of their usual care.

The data to be analysed in this study will be extracted for the 2781 people referred to the memory clinic at Newham University Hospital between 2013 – 2016. This time period has been chosen as a complete set of data is available for these participants. Post 2016 GP referrals to

the memory clinic were managed within a primary care setting so the data does not exist in the hospital database to allow comparison of participant characteristics between referral sources. However the 2013- 2016 dataset remains relevant. The Acute Hospital Dementia CQUIN which introduced and incentivised dementia case finding on admission to hospital in 2013 is now part of the standard contract for NHS Trusts in England, so hospitals continue to identify people on admission to hospital who have not previously sought help for memory problems.

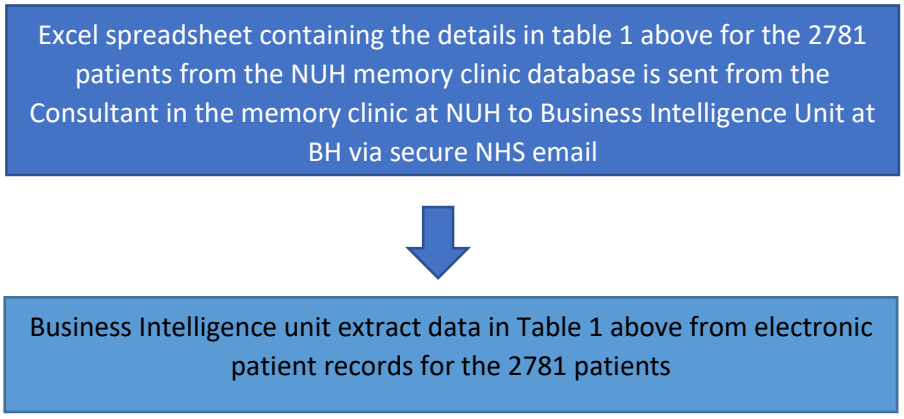
Design

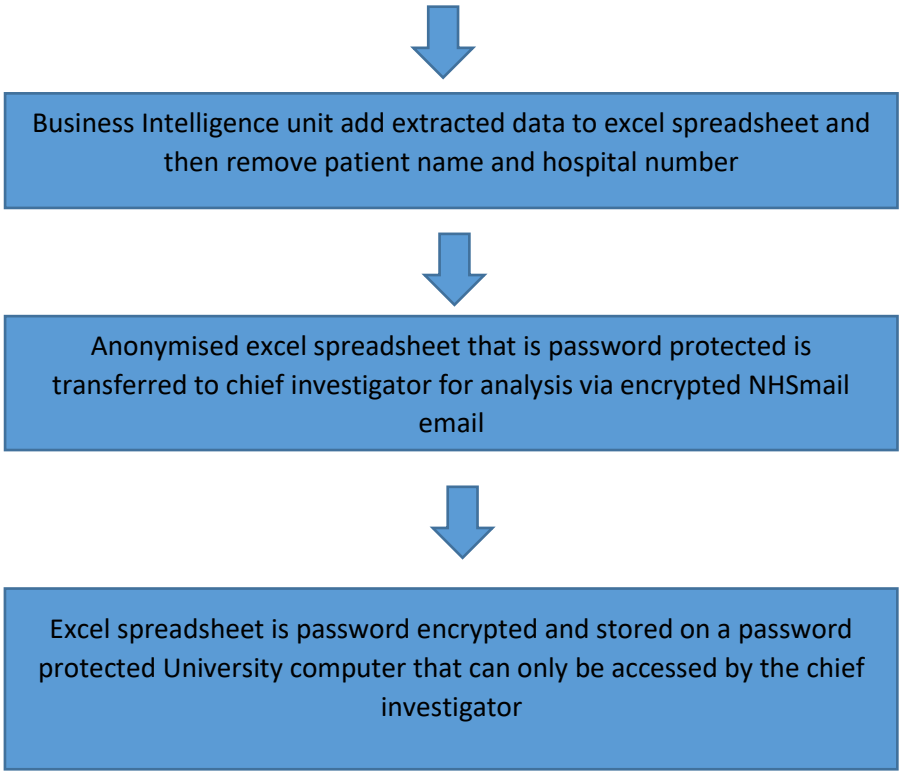
The study will involve statistical analysis of anonymised data that have already been collected as part of the routine care of participants referred to the memory clinic. The data are located in two places – the memory clinic database which is maintained by the Consultant Geriatrician who runs the clinic and the electronic patient records. The data variables to be extracted were determined in conjunction with the lead consultant and the chief investigator's educational supervisors based on the data available, the research questions and what is already known from the relevant literature. The data to be extracted from the clinic database and electronic patient records are shown in table 1.

Table 1 Data to be extracted

Data from clinic database	**Data from electronic patient record**
Age in years	Gender
Diagnosis	Ethnicity
Severity of dementia at time of diagnosis	No of admissions in 12 months pre referral
Referral source	No of admissions 12 months post referral
Plan – includes reason for not being assessed/ diagnosed	Admission diagnosis for admissions in 12 months pre and post referral
	Past medical history problems/ diagnoses
	Month/ Year of death (if appropriate)

Data Management Procedure





Data Analysis

The anonymised data from the excel spreadsheet will be coded by the chief investigator and then transferred to SPSS for analysis. Descriptive data will be reported on the demographic characteristics, diagnosis related information and information related to past medical history, hospital admissions and mortality. Univariate analyses will be conducted to look for a relationship between individual factors and referral pathway, using either chi square or correlations (e.g. Pearsons). If there are sufficient factors that are significantly related on univariate analysis then a multivariate analysis will be conducted.

Practical issues

<u>Access to data</u>

The Consultant Geriatrician in the memory clinic has granted permission for data from the clinic database to be analysed and is happy to transfer the data to the analyst in the Business Intelligence unit. The analyst in the Business Intelligence Unit regularly extracts data related to memory clinic patients in order to demonstrate progress towards dementia related hospital targets and service audits. A meeting with the analyst has confirmed the feasibility and format of the data to be extracted. The manager of the Business Intelligence Unit has given permission for the analyst to extract the data.

Ethical Permissions

Support for the study has been granted from the Information Governance manager and the Caldicott Guardian at Barts Health NHS Trust. An application for HRA approval through the IRAS system to carry out the data analysis will be made.

Transfer and storage of data

Transfer of data between the memory clinic consultant and the Business Intelligence Unit will be via internal secure NHS email. Although the chief investigator will only have access to anonymised data, these data will be transferred via an encrypted NHSMail email. The anonymised dataset will be stored in accordance with City, University of London research data storage policies.

Ethical concerns

The proposed data analysis uses data that were collected as part of the routine care of the participants referred for assessment at the memory clinic. As the data being analysed were collected between 2013 – 2016 the participants were not asked for consent to use their data for research purposes. Due to the retrospective nature of the data being used and the high likelihood that participants will have dementia or another cognitive impairment, it would not be considered practical to contact the participants to request permission to access their data. Asking for consent may also introduce bias as those giving consent for their data to be used may differ from those not giving consent.

However there is no requirement for the chief investigator to access personal data that could be used to identify participants in order to answer the research questions. Therefore only anonymised data will be accessed by the chief investigator. There will be no possible way for the chief investigator to identify the individual that each set of data relates to. Use of anonymised data is considered out of the scope of General Data Protection Regulations but Barts Health GDPR procedures will ensure that the process of anonymisation is carried out appropriately. Approval for the use of anonymised data from the Health Research Authority will be sought.

Timescale

Support and approval from Barts Health - September 2018

HRA approval – October/ November 2018

Data extraction – December 2018 – January 2019

Data analysis – January 2019 – June 2019

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Appendix 20 Phase 3- HRA approval for Quantitative Study

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

[redacted]

HRA and Health and Care

Study title:	**What are the characteristics of people referred to a memory clinic via their GP and via the acute hospital.**
IRAS project ID:	**242277**
Protocol number:	**PhD/18-19/04**
Sponsor	**City, University of London**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS

organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your nonNHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?

You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:
Name: Alison Welton
[redacted]
[redacted]

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **242277**. Please quote this on all correspondence.

Yours sincerely

Miss Lauren Allen
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Alison Welton*
Dr Mays Jawad, Barts Health NHS Trust

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Covering Letter]	1.0	08 October 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Provisional Indemnity]	1.0	17 September 2018
HRA Schedule of Events [HRA Schedule of Events]	1.0	10 October 2018
HRA Statement of Activities [HRA Statement of Activities]	1.0	10 October 2018
IRAS Application Form [IRAS_Form_10102018]		10 October 2018
Other [Good Clinical Practice training certificate]		08 October 2018
Other [Academic Supervisor Ethical Review Form]		20 September 2018
Other [Permission from Memory Clinic Consultant]		19 September 2018
Other [Permission email from BIU]		08 October 2018
Other [Information Governance Approval email]		17 August 2018
Referee's report or other scientific critique report [Review of PhD protocol at upgrade]		05 June 2018
Research protocol or project proposal [Study Protocol]	1.2	19 September 2018
Summary CV for Chief Investigator (CI) [Brief CV]	1.0	08 October 2018
Summary CV for supervisor (student research) [CV Prof Aitken]		08 October 2018
Summary CV for supervisor (student research) [CV Dr Hoe]		08 October 2018
Summary CV for supervisor (student research) [CV Dr Barlow]		08 October 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol summary and flowchart]	1.0	08 October 2018

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	The research involves analysis of previously collected anonymised data only; therefore there is no direct patient

			involvement in the research.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	No funding will be provided to the site.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion	Not Applicable	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations	Not Applicable	No comments

	received for applicable studies		

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one participating site. The direct care team and business analyst at the site will be responsible for collecting and anonymising the data. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A key contact has been identified at the site to liaise with regarding data collection, GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Access arrangements will not be applicable as data will be collected and anonymised by the direct care team and business analyst at the site who have routine access to the data.

Other Information to Aid Study Set Up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.