**FULL/LONG TITLE OF THE STUDY**

Primary care led post-diagnostic dementia care: developing evidence-based, person-centred sustainable models for future care

**SHORT STUDY TITLE / ACRONYM**

Primary care led support in dementia: Developing best practice (PriDem)

**PROTOCOL VERSION NUMBER AND DATE**

Version 6.0, 23.11.2020

# RESEARCH REFERENCE NUMBERS

|  |  |
| --- | --- |
| IRAS Project ID | 238921 |
| SPONSORS Number | RES-18-034 |
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# SIGNATURE PAGE

The undersigned 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 Standard Operating Procedures (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 publically 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.

|  |
| --- |
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| Committees | Programme management board (PMB)External steering committee (ESC)Patient and public programme advisory board (PPAB) |

# STUDY SUMMARY

|  |  |
| --- | --- |
| Study Title | Primary care led post diagnostic dementia care: developing evidence-based, person-centred sustainable models for future care |
| Internal ref. no. (or short title) | Primary care led support in dementia: Developing best practice (PriDem) |
| Study Design | Mixed methods comprising: interviews; focus groups and observation |
| Study Participants | Service managers, commissioners, frontline staff, people with dementia and family members |
| Planned Size of Sample (if applicable) | Up to a total of 104 participantsUp to 40 service managers and commissioners (interviews)Up to 24 frontline staff (focus groups & observation)Up to 40 people with dementia & family members (interviews & observation)Up to 18 staff from linked local services (interviews or focus groups) |
| Follow-up duration (if applicable) | Following initial interviews with service managers and commissioners, up to six services will be invited to take part in a more in-depth study comprising interviews and observation. Services involved in this phase will be followed up over a 4 month period. Individual participants will usually be involved in a single interview or focus group although some frontline staff, people with dementia and family members may also be observed. Selected participants in the interviews and focus groups may be invited to participate in the subsequent task groups.  |
| Planned Study Period | 24 months |
| Research Question/Aim(s) | The overall aim of WS2 and 3 is to identify core and desirable components of primary care led post diagnostic dementia care which will maintain and improve quality of life for people with dementia and their families. These components will be tested in subsequent workstreams. |

**FUNDING AND SUPPORT IN KIND**

|  |  |
| --- | --- |
| **FUNDER(S)**Katherine GrayResearch Grants ManagerAlzheimer’s Society43-44 Crutched FriarsLondon EC3N 2AETel: 0207 4235133Email: Katherine.gray@alzheimers.org.uk | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN**£1,680,224.55Two years of funding initially awarded. Remaining two years of funding awarded subject to satisfactory review at 24 months.  |

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| **KEY WORDS:** | Dementia; family members; post diagnostic support; primary care; person-centred care; professional perspectives |

# GLOSSARY OF ABBREVIATIONS

|  |  |
| --- | --- |
| CCG | Clinical Commissioning Group |
| CI | Chief Investigator |
| DCC | Dementia Care Community |
| DeNDRoN | NIHR Dementias and Neurodegeneration Specialty |
| ESC | External Steering Committee |
| GCP | Good Clinical Practice  |
| GP | General practitioner |
| HRA | Health Research Authority |
| ICMJE | International Committee of Medical Journal Editors |
| IRAS | Integrated Research Application System |
| JDR | Join Dementia Research |
| LTC | Long Term Condition |
| MSNAP | Memory Services National Accreditation Programme  |
| NDS | National Dementia Strategy |
| NHS | National Health Service |
| NICE | National Institute for Health and Care Excellence |
| NIHR | National Institute for Health Research |
| PIS | Participant Information Sheet |
| PMB | Programme Management Board |
| PPAB | Patient and Public Advisory Board |
| PPI | Patient and Public Involvement |
| QOF | Quality Outcomes Framework |
| RCT | Randomised Controlled Trial |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |
| UK | United Kingdom |
| WAR | World Alzheimer Report |
| WS | Workstream |

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# BACKGROUND

Post diagnostic dementia care was recently defined as *a ‘system of holistic, integrated continuing care in the context of declining function and increasing needs of family carers’* (1)*.* Our aim is to address the concerning findings of the Alzheimer’s Society report *Dementia 2015: aiming higher to transform lives* by increasing the proportion of families living with dementia who receive good quality support (2). In a timely manner, our proposed programme targets the recommendations of the 2016 World Alzheimer Report (WAR), *Improving healthcare for people living with dementia; coverage, quality and costs now and in the future,* which states that the current specialist-led, healthcare model for post-diagnostic dementia care is unsustainable and unaffordable (1). The report highlights the urgent need for more efficient use of existing resources via the introduction of a task-shifted and task-sharedmodel where primary care takes lead responsibility for post diagnostic care coordination, thus facilitating more appropriate and timely specialist care input as and when required (see Box 1).

**Box 1 World Alzheimer Report 2016: task-shifted and task-shared dementia care pathway (1)**

**Diagnosis:** mostly by general practitioners (GPs) and dementia case managers

**Post diagnostic care:**

* 1. i) Initial treatment /early post diagnostic care: mostly in primary care +/- dementia case manager1
* anti-dementia drugs assessment
* post diagnostic support package
* carer wellbeing and support
1. Ongoing, continuing care: mostly in primary care +/- dementia case manager1
	* + behavioural and psychological symptom management
		+ future care planning
		+ co-morbidities management
		+ maintenance of physical function and emotional wellbeing
	1. iii) End of life care: GP with primary care team and specialist support (palliative care)

1 Specialist care input for complex patients and/or challenging areas of clinical care

**Post diagnostic dementia care**: In 2015, there were approximately 850,000 people with dementia in the UK; with care costs estimated at £26 billion with £4.3 billion from the National Health Service (NHS) (3). People with dementia and their families often receive poorly integrated and inadequate support after receiving a diagnosis (4, 5); a recent Alzheimer’s Society report found 53% of people with dementia felt anxious/depressed and 49% received insufficient support, a finding echoed by half of the approximately 1000 GPs also surveyed (2). Research (6-11) and policy (12, 13) continue to highlight the need to improve post diagnostic dementia care both in terms of quality of care and equity of access by reducing geographical inequalities (i.e. the post code lottery).The components of care which are core to good practice, and the optimal timing of these, need further definition; a systematic review listed the following as essential: timely and individualised information provision (e.g. assistive technology, financial benefits), signposting to practical support such as statutory/voluntary services and timely access to specialist, secondary care services (14). The WAR (2016) addresses the importance of improving the quality of healthcare for people living with dementia and their families but also the urgent need to develop and implement cost effective, holistic models of care for both high, and low, income countries that are sustainable in view of rapidly ageing populations (1). It has long been acknowledged that primary care led healthcare systems deliver more efficient and equitable services than secondary care (15), with healthier, more satisfied patients, for lower cost and with fewer inequalities in both health and access to care (16, 17).

**UK dementia care**: In England, primary care is now central to future service planning and provision following the introduction of GP led, clinical commissioning groups (CCGs) that focus on meeting local care needs (18). This follows a policy shift over the last decade towards a primary care led system for the management of common Long Term Conditions (LTCs) (e.g. diabetes and depression) supported by national initiatives such as the Quality Outcomes Framework (QOF) (19). However dementia care remains largely secondary care led (20), despite the potential for primary care to play a key role throughout the illness trajectory (6-11). Diagnosis and early intervention are usually via specialist memory clinics (although neurology and geriatrics can be involved) before discharge to primary care (21-23). Memory clinics are effective diagnostic services but there is currently no evidence to demonstrate their effectiveness in terms of post diagnostic care (23, 24). Despite quality improvement initiatives such as the National Dementia Strategy (NDS) and Memory Services National Accreditation Programme (MSNAP), people diagnosed with dementia, and their families, still experience considerable anxiety, diagnostic delays and geographical inequity in access to care as secondary care struggles to meet the increased demand from our ageing society (25-27). In primary care, although GPs are compelled to undertake an annual dementia review via QOF, the lack of a standardized, evidence-based approach to this process further increases care inequalities (28). Despite national commissioning guidance (29), community led dementia care remains complex, poorly integrated and highly variable (25-27, 30-32). In England, new initiatives recommended by the NDS (e.g. dementia advisors and peer support) have struggled to be sustainable despite positive feedback from people with dementia and their families (32).

**Primary care-led Long Term Conditions (LTC) care:** Dementia, although an illness with specific clinical challenges such as behavioural problems and declining mental capacity, has much in common with other LTCs, for example, optimising medications and managing physical co-morbidities. In the past 20 years collaborative, shared care models for LTC, where primary care leads, or is an equal partner with secondary care, have been introduced and successfully embedded in NHS practice. In terms of the organisation of LTC care, six essential components have been defined:

1) Health system organization (i.e. providing leadership for securing resources; removing barriers to care).

2) Self-management support (i.e. facilitating skills-based learning and patient empowerment).

3) Decision support (i.e. providing guidance for implementing evidence-based care).

4) Delivery system design (i.e. coordinating care processes).

5) Clinical information systems (i.e. tracking progress through reporting outcomes to patients and providers).

6) Community resources and policies (i.e. sustaining care by using community-based resources and public health policy) (33).

Critically examining such generic models, which can sometimes incorporate social care and voluntary sector support, could help identify key components (e.g. record-sharing, personalised care planning and care coordination), for sustainable primary care-led model(s) for dementia care (34).

**Primary care coordinated interventions for post diagnostic dementia care:** A recent randomised controlled trial (RCT) from The Netherlands, comparing ‘normal’ GP led post diagnostic dementia care with specialist memory clinic care, showed no significant difference between the two approaches (35). However RCTs comparing usual GP care with ‘enhanced primary care’, either via educational support (36) or linkage with expert networks (37), have been largely ineffective although intervention development was poorly described in both studies. In terms of examples of innovative primary care led dementia services, a range of national and international examples has been described including GP led diagnostic services (38-42), primary care based specialist led clinics (43, 44) and primary care-based case management interventions (45-47). Nonetheless, most were small, localised services with limited critical evaluation (1, 48), thus lacking the evidence base essential to support wider implementation (49). Integrated community care pathways have been suggested as a quality improvement initiative (50, 51) for example, Alzheimer’s Scotland’s 5/8 Pillars Models (13, 52) and Brisbane Care Pathways (53). In England, new national guidance on dementia care from the National Institute for Health and Care Excellence (NICE) has recently been published (<https://www.nice.org.uk/guidance/ng97> ). Although this is based on a thorough evidence review, it lacks practical advice on how to successfully implement recommended good practice into usual care. From a cost effectiveness perspective, ongoing research led by co-applicant Knapp is aiming to produce guidance on affordable and sustainable models of dementia care ([www.modem-dementia.org.uk](http://www.modem-dementia.org.uk/)). PriDem will use these existing effectiveness and cost effectiveness ‘datasets’, with new data, to address its aims and objectives.

# 2 RATIONALE

Dementia is a global health and economic priority (54). In the UK, dementia has received substantial political attention. Initially in England this was via the NDS and a unique Prime Minister’s Dementia Challenge, both largely focused on earlier diagnosis (55, 56). More recently there has been a significant policy shift to improving post diagnostic care (1)*,* with national recommendations now focusing on:

1. reducing the number of people developing dementia via public health programmes (57) as research confirms the role of vascular and other risk factors (58-60)
2. post diagnostic care via a GP led approach (61) as a more cost effective model (62).

# 3 RESEARCH QUESTION/AIMS

The overall aim of the PriDem programme is to develop and evaluate acceptable, feasible and hopefully sustainable model(s) of evidence based, person-centred, primary care led post diagnostic dementia care to maintain and improve quality of life for people with dementia and their families. We will adopt the WAR 2016 holistic definition of post diagnostic care, beginning from the point of diagnosis and continuing throughout the illness trajectory. Although PriDem will be primarily conducted in England within a specific health care setting (NHS), we anticipate our key findings, “*core components of good practice for sustainable primary care led, post diagnostic dementia care*”, will be of relevance to other care settings globally (1). An overview of the entire PriDem programme is given below, but this protocol relates only to WS2 and WS3.

**WS1: Current sustainable primary care-led models of long term conditions and dementia care (1-18m).**

WS1.1: Scoping reviews: successful primary care led models of long term conditions (LTC) and dementia care.

WS1.2: Mapping exercise of existing national primary/community care led models of post diagnostic dementia care: e-survey.

**WS2: Stakeholder experiences of current post diagnostic dementia care and proposed future models of best practice** (1-20m).

WS2.1: Current and proposed models of primary care led, post diagnostic dementia care: views of service commissioners and service providers.

WS2.2: Current and proposed models of primary care led, post diagnostic dementia care: views of service users (people with dementia and their family members) and frontline staff.

**WS3: Development of a primary care led model(s) for evidence-based, person-centred post diagnostic dementia care** (m 18-28).

WS3.1: Development of prototype model(s) for primary care led post diagnostic dementia care.

WS3.2: Model(s) refinement: task groups with service users, providers and commissioners

**WS4: Feasibility study and implementation phase** (m25-48).

WS4.1: Feasibility study.

WS4.2: Implementation phase evaluation.

**WS5: Cost impact of the core intervention and associated models** (m15-33).

WS5.1: Cost analysis of health economic modelling of existing model(s) of primary care led post diagnostic dementia care.

WS5.2: Cost analysis and health economic modelling of model(s), developed in WS3, of primary care led post diagnostic dementia care.

**WS6: Pathways to impact: translation of key findings into policy and practice** (m1-48).

To ensure key research findings are translated into smarter, swifter outputs of relevance to policy and practice we will work collaboratively with the Alzheimer’s Society, our dementia care community (DCC) and partner organisations throughout the programme.

Separate protocols and IRAS applications will be submitted for the e-survey (WS1) and feasibility study and implementation phase (WS4).

## Aim

The overall aim of WS2 and 3 of the PriDem programme is to identify core and desirable components of primary care led post diagnostic dementia care which will maintain and improve quality of life for people with dementia and their families.

## 3.2 Outcome

The outcome will be an agreed list of evidence based components of best practice primary care led post diagnostic care and strategies through which these components can be implemented in the feasibility study in WS4.

# 4. STAKEHOLDER EXPERIENCES OF CURRENT POST DIAGNOSTIC DEMENTIA CARE AND PROPOSED FUTURE MODELS OF GOOD PRACTICE (WORKSTREAM 2)

# 4.1 Design and methods

This workstream uses qualitative methods (semi-structured interviews, focus groups and observation) and adopts a realist approach (63). This will enable us to capture and critically explore multiple perspectives of post diagnostic support for people with dementia, in order to understand what works well and for whom. As well as providing a detailed description of the views of different stakeholders, the iterative nature of the data collection and analysis will enable us to develop explanatory insights about the individual and organisational facilitators and barriers to such care.

Three complementary methods will be used to enable us to develop an in-depth understanding of selected service models from the perspectives of different stakeholders:

* Semi-structured interviews and focus groups with professionals commissioning or managing a range of models of post diagnostic dementia care.
* Focus groups and/or semi-structured interviews with professionals delivering selected services and with people with dementia and family members.
* Observation of routine service delivery within selected services.

## 4.2 Study setting

WS2.1 will include services from across the UK. We anticipate that no more than one or two professionals would be recruited from each NHS Trust, Local Authority or non-statutory agency.

WS2.2 will focus on up to six services providing diverse models of post diagnostic dementia care. Services will be selected using the principles of purposive sampling (64), drawing on data from WS2.1 and the literature reviews in WS1. We will aim to include services which:

* Focus on different points in the illness trajectory.
* Are funded by different service providers (health, social care, third sector organisations).
* Are delivered in the home and elsewhere.
* Are used by different demographic groups.

For pragmatic reasons, only sites in England will be included in WS2.2.

## 4.3 Sampling

### 4.3.1 Eligibility criteria

WS2.1:The study population for WS2.1 will be professionals who are responsible for managing or commissioning a service providing post diagnostic support to people with dementia across the UK.

WS2.2**:** Up to six services will be purposively sampled from those identified in WS2.1 for detailed study. Frontline staff working in these services, and people with dementia and family members in receipt of these services will be eligible for participation. Staff working in local services linked to the six selected services will also be eligible for participation.

People with a diagnosis of dementia and their family members who are members of the Join Dementia Research (JDR) register and live in North East England will also be eligible to take part in an interview.

People with dementia and family members will be able to participate independently of one another.

### 4.3.2 Exclusion criteria

WS2.1:Service managers or commissioners who do not respond to an invitation to participate after three contact attempts (using a mixture of email and telephone) will not be included.

WS2.2:Frontline staff who do not provide post diagnostic support will not be eligible. Service users who do not have a diagnosis of dementia will not be eligible; similarly family members of such service users will be excluded.

People with dementia who are unable to give informed consent to observation, whose opinion on research participation is not recorded in the notes maintained by the participating service and who do not attend with a companion who can give an opinion on their behalf will not be eligible for observation.

People with dementia who do not have the capacity to consent for themselves will not be eligible for focus groups or interviews.

Potential participants who cannot communicate in English will not be eligible for focus groups or interviews.

Potential participants who decline to take part will be excluded.

### 4.3.3 Sample size

WS2.1: Up to 40 service managers and commissioners across the UK. Participants will include those working in the NHS (primary and secondary care), social care (local authorities) and third sector (for example Alzheimer’s Society, Dementia UK; Carers UK; Anchor; Housing 21).

WS2.2: Up to six services in England will be selected from those participating in WS2.1 for detailed study in WS2.2. We will arrange one focus group for frontline staff in each of these services and offer individual interviews to key members of staff unable to attend the focus group. We anticipate recruiting between two and six members of staff from each site (giving an anticipated total of around 24 frontline staff). We anticipate recruiting between zero and four staff from linked local services from each site according to the circumstances of the individual service (giving an anticipated total of around 18 staff from linked local services).

We will aim to recruit around 40 people with dementia and/or family members.

As qualitative research, this study is not designed to capture a statistically significant sample. Sampling will focus on collecting a broad range of views and experiences from a range of services. We have estimated sample sizes based on our previous experience; data collection will continue, however, until the point that further data collection does not lead to new insights.

### 4.3.4 Sampling technique

WS2.1: A purposive approach to sampling (64) will be used for interviews with the aim of achieving a maximum variation sample which includes diverse models of post diagnostic support including well-established and new initiatives and those serving different populations (rural, inner city, minority ethnic groups, and younger people with dementia). The sample will be informed by: the preliminary scoping reviews conducted in WS1; members of the DCC and the project team; linked personnel at the Alzheimer’s Society; and review of NICE guidance and other policy documents. In addition we will conduct up to two focus groups with convenience samples to encourage debate and discussion between service managers and commissioners. Potential participants will be drawn from existing groups of service managers and commissioners. The group convenor will provide members with a PIS and ask for volunteers. If sufficient numbers agree to take part, a focus group will be arranged at a time and place convenient to participants (usually after an existing meeting).

WS2.2: All frontline staff meeting the eligibility criteria in the selected services will be approached and invited to take part in the study. In the event of oversubscription to the planned focus group, we will use the principles of purposive sampling to select participants from a range of backgrounds and with differing levels of experience.

We will use a purposive approach to sampling staff from linked local services with the aim of achieving a range of perspectives on the fit of the service within the wider local context.

Convenience samples of people with dementia and family members will be used. All those using the service on selected dates will be eligible for inclusion in the observation. Those who agree to the observation may be invited to take part in an interview or focus group at the end of the period of observation. This approach has been used in previous studies and has the benefit of providing the researcher with contextual information which can be useful in prompting respondents during subsequent interviews or focus groups.

Since not all of those who agree to observation will wish to be interviewed we will recruit additional participants via service managers of the selected services. We will ask service managers to identify current or recent (within the last three months) people with dementia and family members with diverse experience in terms of their use of the service, point on the dementia trajectory and, for family members, relationship to the person with dementia.

We will also use Join Dementia Research (JDR) as a recruitment tool. This is an online self-registration service that enables volunteers with memory problems or dementia, family members of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research. The purpose of JDR is to allow such volunteers to be identified by researchers as potentially eligible for their studies. Researchers can then contact volunteers, in line with the volunteers' preferred method of contact, to further discuss potential inclusion. JDR is funded by Department of Health working in partnership with the charities Alzheimer Scotland, Alzheimer’s Research UK and Alzheimer’s Society and is Health Research Authority (HRA) endorsed. The online service and all associated documentation, methods of contacting volunteers and handling of data, were reviewed by a specially convened HRA committee which included experts in research ethics, data protection and information governance. Formal endorsement was issued by the HRA in a letter dated 20 May 2014.

### 4.3.5 Sample identification

WS2.1: To ensure that a wide range models of service organization are included in the interviews, we will use a number of different approaches to identifying potential participants, including:

* Preliminary scoping reviews conducted as part of WS1
* Members of the DCC
* Members of the project team and linked personnel at the Alzheimer’s Society
* Review of NICE guidance and other policy documents.

The focus groups will be with existing groups meeting in North East England.

The WS2 team will identify any existing information about services managed or commissioned by potential participants through desk-based research. These details will then be summarized in structured tables to facilitate sampling and ensure that a wide range of service models is included.

WS2.2: Services for participation in WS2.2 will be selected using the principles of purposive sampling with the aim of including services serving different populations and providing diverse interventions.

Frontline staff will be identified by service managers. We will identify potentially relevant staff from linked local services through discussion with service managers, frontline staff focus groups, and observation. The sample of people with dementia and family members for observation will be drawn from those using the service on dates agreed for observation with the service manager/frontline staff. The sample for interview will be identified through the observation, service managers or JDR.

### 4.4 Approach and recruitment

WS2.1: The contact details of service managers and commissioners will generally be in the public domain. If we cannot identify a named contact via the internet, we will contact the service or CCG to identify the most appropriate contact so that a personal invitation can be sent. The initial approach will be via email and will include:

* A short invitation email
* A participant information sheet (PIS) about WS2
* A participant information sheet giving an overview of the programme.

The email will be followed up by telephone approximately one week later; this will allow the potential participant the opportunity to ask questions and seek clarification on participation if required. If the potential participant is willing to be interviewed, a time and date for the interview will be arranged. At the outset of the interview, consent for recording the interview will be confirmed. If a potential participant cannot be contacted to confirm or decline participation after three attempts, s/he will be excluded from the study.

Initial contact with potential focus group members will be made by the group convenor to whom informal expressions of interest will be made. If sufficient members agree to participate, we will negotiate the most appropriate time and place for a focus group with the group convenor (most probably after an existing meeting).

WS2.2: Service managers in the services selected for WS2.2 will distribute an information pack to frontline staff comprising:

* A participant information sheet (PIS)
* An opt-in form
* A prepaid envelope addressed to the WS2 team.

Where possible, the WS2 team will visit selected services to brief staff on the study and to answer any questions. A poster will also be provided for each service to increase staff and service user awareness of the study. The opt-in form will include details of role and experience to facilitate sampling in the event of oversubscription and will allow staff to opt into observation and/or focus group.

Frontline staff who return the opt-in form will be contacted either by email or telephone to answer any questions, confirm the time and date of the focus group and, if appropriate, negotiate arrangements for observation. The views of frontline staff will primarily be collected through focus groups, although some face-to-face interviews may be arranged for key members of staff who are unable to attend the focus group.

A similar process will be used for staff in linked local services. An information pack will be distributed by the research team to potential participants by email, post or in person. Staff who return the opt-in form will be contacted to answer any questions and confirm a date, time, and location for an interview or focus group if this is more appropriate (e.g. if there is an existing MDT).

The approach and recruitment of people with dementia and their families to observation will generally be delegated to staff working in the selected services. Based on our previous experience of conducting observation, we feel this is the most pragmatic approach. We need to balance the:

* Rights of people with dementia and their family members to have a choice over participation
* Intrusiveness of the proposed research
* Need to disrupt participating services as little as possible
* Need to avoid placing unrealistic demands on professionals.

We are not seeking formal, written informed consent for observation, but rather seeking to ensure that people with dementia and their families are able to decline having an observer present and that the process of observation does not have a negative effect on their interaction with the professional delivering the service. To achieve these aims we propose that the researchers are guided by people who know the person with dementia well - namely professionals and family members. All people with dementia will be asked to give consent appropriate to their level of understanding, with account being taken of verbal and non−verbal communication in determining willingness to participate.

We have developed a flowchart for eligibility and consent for the observation which not only relies on professionals’ assessment of capacity, but also checks whether the person with dementia has made an advance statement or expressed preferences about their future involvement in research and considers the view of family members accompanying the person with dementia wherever possible. Furthermore, both the researcher and member of staff will monitor the behaviour of the person with dementia throughout the session for any signs of distress or other indicators that the presence of the researcher is having a negative effect. In the event of such signs, the researcher will either offer to withdraw or may be asked by the professional to withdraw. Similarly if the companion feels that the presence of the researcher is detrimental, s/he may also ask the researcher to withdraw.

While staff working in participating services may not have received formal training in the assessment of mental capacity, we anticipate that assessing the extent to which a person with dementia has understood information provided and is able to choose between different options will be an integral part of the day to day work of frontline staff. We therefore think that staff will be experienced in making such informal assessments of capacity. Furthermore, they are likely to have previously met the person with dementia and have access to background information which may inform their ability to judge whether the person has understood that they are being asked to take part in research and what is involved. No personal details of people with dementia will be recorded in field notes beyond age (years), gender, and type of dementia; for family members only gender and relationship to the person with dementia will be recorded.

People with dementia and family members attending the service or due to receive a home visit on the selected observation dates will be approached by the staff member providing the intervention. The staff member will follow a flowchart process to consider if a person with dementia has capacity to consent to the observation. Where the person is thought to be unable to give consent, the staff member will draw on any recorded preferences about participation in research and advice from a family member where no preferences are recorded. The staff member will explain that a researcher would like to observe a session and will seek verbal agreement to this. Where planned services are delivered in the home, potential participants will be provided with this explanation and an information sheet at least 48 hours prior to the date of observation wherever possible. Where services are provided in a clinic or community setting, potential participants will be given an information sheet on arrival for their appointment. We will also provide a poster for display in each participating service. This will provide information about the study and the possibility that service users and family members may be asked if a researcher can sit in on their session. We are aware that some services operate on a more informal basis without prior contact with attendees e.g. a drop-in service; if this type of service is included, we will discuss the most appropriate strategy for approaching potential participants with the service manager. If necessary we would seek relevant approvals via the amendment process.

People with dementia (with capacity to consent for themselves) and any family members who are observed whilst using the service may be invited to take part in an interview at the end of the session by the researcher. They will be offered a PIS about the interview and the researcher will stress that they are under no obligation to take part in this additional part of the study. If they are willing to consider participation, the researcher will seek verbal consent to contact them by telephone once they have had time to read the PIS. At least 24 hours will be given for potential participants to read the PIS.

Since we may not be able to recruit the required number of people with dementia and family members through observation, we will ask service managers to identify current or recent (within the last three months) service users. People with dementia and family members thus identified who will provided with an Information pack by the service manager which will include:

* An invitation letter
* A participant information sheet (PIS)
* An opt-in form
* A prepaid envelope addressed to the WS2 team.

Potential participants who return the opt-in form will be contacted by telephone.

We will additionally use JDR to recruit people with dementia and family members. JDR is an online self-registration service that enables volunteers with memory problems or dementia, family members of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research. As part of this registration process, participants provide some personal information, such as name, date of birth, contact details and some basic details about their health. Participants consent for this information to be used to find studies that might be a suitable match for them. JDR staff then identify volunteers who meet the eligibility criteria for new studies (potential matches). An email is sent to these potential matches to let them know they are potentially eligible for a new study and can access a brief summary of the study (the JDR advert). A member of the research team will be allocated an ID and trained to use JDR. This researcher will be able to view potential matches and contact them to discuss the study further and see if potential participants are interested and suitable to take part. Those who express an interest will be sent a PIS either by post or email. At least 24 hours will be given for potential participants to read the PIS before the follow up telephone call

Regardless of the method used to identify participants, at the follow up telephone call, the researcher would discuss the study and check whether the potential participant is interested. If the person is willing to take part, the researcher would then arrange a time for an interview or focus group.

Interviews would usually take place in the participant’s home, or other venue of their choice. Participants required to travel to focus groups will be reimbursed for reasonable travel expenses. Family members will be reimbursed for the costs of any additional care needed to enable their participation in the study.

### 4.5 **Consent**

All researchers will have completed training on Good Clinical Practice, Informed Consent and the Mental Capacity Act.

WS2.1: We will seek written consent from service managers and commissioners for participation in interviews. Professionals who agree to take part will be sent a study information and consent form and asked to sign and return this prior to the interview. However, if a completed consent form has not been returned before a telephone interview is scheduled, verbal consent to participation will be recorded as part of the interview. Written consent will be sought from all participants immediately prior to the focus groups.

WS2.2: Written consent will be sought from all professionals prior to observation and/or interview or focus group participation.

As previously described, verbal consent will be sought from people with dementia and their family members for observation; those who agree to take part in an interview or focus group will be asked to give written informed consent to participation. A checklist adapted from a previous study will be used to guide the researchers in assessing capacity to consent to the study. Only people with dementia with capacity to give informed consent will be eligible for interview.

## 4.6 Data collection and management

Data will be collected by research associates working on WS2 under the supervision of the WS leads (CB/JA).

### 4.6.1 Interviews and focus groups

Interviews and focus groups with commissioners and service managers will explore participant views on i) components of post diagnostic care; ii) the extent to which the service(s) they manage or commission address these components; iii) proposed models of good practice (65); iv) ideas for service development; and v) factors which promote user or person-centred services and influence successful implementation and sustainability of services, particularly those led by primary care.

We anticipate that the views of frontline staff will primarily be collected through focus groups, although some face-to-face interviews may be arranged for key members of staff who are unable to attend the focus group. We will explore the views of frontline staff on i) the timing, content and delivery of post diagnostic care; ii) proposed models of good practice (65); iii) factors which promote user or person-centred services and influence successful implementation and sustainability of services.

Interviews/focus groups with staff from linked local services will aim to capture i) their views on the specified service; ii) the ‘fit’ of the service with their own service and with others within the local context; iii) their views on post diagnostic care for dementia more generally.

The views of people with dementia and family members will primarily be explored through face-to-face interviews (either individually or jointly depending on their preferences). We may, however, arrange a focus group of people with dementia and/or family members in some circumstances (e.g. in services where such groups are already established). Regardless of the method of data collection, we will explore participant views on: i) services received and how these are coordinated; ii) the timing, content and delivery of post diagnostic care; iii) proposed models of good practice (65); and iv) factors which promote user-centred services.

Topic guides will be developed initially by the WS2 team and reviewed by members of the DCC and PMB. The WS2 team will review the topic guide after the first few interviews to ensure that all key areas are included.

We anticipate that interviews with commissioners or service managers will take approximately 30 minutes; focus groups with commissioners and service managers will last up to 60 minutes to allow for interaction between members and feedback on the topic guide. Focus groups with frontline staff will last up to one hour; and interviews with people with dementia and family members will last around 40 minutes. It may not be feasible to cover all areas of the topic guide with all respondents; the researchers will be sensitive to potential respondent fatigue and time limitations and will tailor the interview accordingly, focusing on those areas which seem most relevant to the individual respondent.

Interviews will be audio-recorded and transcribed verbatim by an external transcription service (UK Transcription Service). Files for transcription will be uploaded via a 256 bit SSL secured website which has been independently audited by a 3rd party security firm. Details of the security and confidentiality agreement are provided in Appendix 1. Transcripts will be checked and anonymised by the WS2 team, following which audio recordings will be destroyed. Transcripts will be identified only by the unique study identifier and will be stored on a University networked computer accessible only by password. Printed transcripts will be stored in University offices accessible only by smartcard. Only those researchers involved in data collection in WS2 will have access to non-anonymised data.

### 4.6.2 Observation

We will briefly observe each service on up to three occasions to gain insight into how the model is delivered in practice. The observations will enable us to consider whether and how aspects of care highlighted in existing literature, by service managers and commissioners and by our DCC are enacted in practice.

We will aim to include observation of interactions between professionals (e.g. team meetings) and direct service delivery to people with dementia and/or family members. We will avoid imposing structure on our observations, rather writing detailed field notes immediately after the observation period (66). As ‘outsiders’, our intention is to question practices and assumptions that are taken for granted. Through observation, supplemented by informal conversations, we will examine the organisation and structure of post diagnostic care (what happens to whom, where and when; extent to which programmes are tailored to individuals; focus and duration of interventions) and identify factors that constrain/promote the delivery of good quality care.

## 4.7 Data analysis

The formal data for analysis will consist of anonymised transcripts, fieldnotes of observation and reflective notes made by researchers. Analysis will take place in data workshops involving the WS2 team and will be presented to the wider project team and the DCC for discussion. The constant comparative method of analysis will be used with an iterative process of data collection and analysis. This will allow initial themes and ideas to be explored in more depth in subsequent interviews, focus groups and observation. A coding frame will be developed during the data workshops and the interviews will be coded by the WS2 research associates. A software package (QSR NVivo 11) will be used to facilitate data management. Data from different stakeholders will be used to compare their perspectives on good quality care and identify facilitators/barriers to such care.

Though initial analysis will be carried out on the datasets from each stakeholder group independently of one another, the findings will subsequently be integrated. The integrative analysis will then be summarised in reports and presentations to inform the development of a primary care coordinated model(s) for evidence-based, person-centred post diagnostic dementia care development process in WS3.

# 5 DEVELOPMENT OF AN EVIDENCE-BASED PRIMARY CARE-LED MODEL(S) FOR POST DIAGNOSTIC DEMENTIA CARE (WORKSTREAM 3)

## 5.1 Design and methods

A co-design approach will be used, enabling us to gain the insights and experiences of a wide range of practitioners (67). The process will follow the Medical Research Council’s recommendations for the development of complex interventions (68). An overview of the process is provided in Figure 1.

**Figure 1 Overview of WS3**

|  |  |  |  |
| --- | --- | --- | --- |
| **Phase** | **Participants** | **Methods** | **Outputs** |
| Development | Research team | Data synthesis workshops | Identification of core components of model(s) |
| DCC members | Iterative co-design process with up to four meetings held via video conferencing | Discussion of core & desirable components; identification of omissions. matrix of key tasks & essential skills |
|   |  |  |
| Refinement | External and independent stakeholders | Task group(s) held via video conferencing | Refined prototype model; recommendations regarding feasibility, acceptability and training needs |
| DCC members | Meeting(s) held via video conferencing | Review & refinement of prototype model and recommendations  |
| Research team | Workshop(s) held via video conferencing | Final refinements to produce version for testing in WS4 |

Using NICE guidance (65) and key findings from other workstreams, a series of data synthesis workshops will be held with all co-applicants, facilitated by WS3 leads to identify initial core components of the prototype model(s). The output of these meetings will be draft model(s) for discussion and refinement. DCC members will review the draft model(s) and review components to ensure they are comprehensive. This will be an iterative process to allow for the refinement of ideas over a series of up to 4 meetings (69).

Following development of the prototype, a series of task groups (70) will be held with external and independent key stakeholders from across the UK. The groups will focus on critiquing the components of post diagnostic support, checking them for omissions, validity and feasibility and making suggestions for refinement. The task groups will also be asked to consider the variability in practices and practitioners; and subsequently which components favour adoption and which may require supporting educational materials and/or additional training and resources. The comments and suggestions from the task groups will be returned to the DCC for final review. Following this, the team will finalise the components for testing in WS4.

Due to changes in dementia care in response to the COVID-19 pandemic, follow-up interviews will be held with professional participants to ensure that the proposed intervention is fit for purpose.

## 5.2 Study setting

In light of the COVID-19 pandemic, some WS3 activities will now be held using video conferencing. People with dementia and carers will be offered training and a practice video session prior to meetings of the DCC or task groups or may choose to take part in one-to-one telephone calls if they would prefer this. Follow-up interviews will be held either via video conferencing or telephone, according to participant preference.

## 5.3 Sampling

All co-applicants and research staff will be eligible to participate in the data synthesis workshops. All DCC members will be invited to contribute to DCC meetings relating to intervention development. All professional participants from WS2 will be eligible to take part in a follow-up interview; if they are unavailable, a colleague will be eligible to take part in their place.

We will identify potential members of the task groups through workstreams 1 and 2, the Alzheimer’s Society, Age UK, local service providers and commissioners, and relevant royal colleges. Membership will include people with mild to moderate dementia, family members (including those currently caring for a person with dementia and bereaved family members), primary and secondary care professionals, community service providers (Alzheimer’s Society and other voluntary sector groups) and service commissioners. Recruitment will ensure a representative range of professionals who reflect the key skills and tasks identified by the team workshops.

Potential participants who do not respond to an invitation to participate after three contact attempts (using a mixture of email and telephone) will not be included.

### 5.3.1 Sample size

The data synthesis workshops will include up to 20 participants, depending on availability. All members of the DCC will be invited to participate in meetings about the intervention (approximately 40 individuals). The number and size of task groups will be informed by the proposed content and delivery of the components of post diagnostic support, but we anticipate holding up to eight task groups, each involving up to six individuals. Task groups were planned to last for half a day; however, we do not consider a meeting of this length to be appropriate for video conferencing. In addition to reducing the number of participants in the task groups, task groups may meet more than once. We may also reconfigure membership of the task groups for subsequent meetings, for example, arranging groups with more homogeneous backgrounds to explore certain issues in more depth. Some topics may also be particularly relevant to certain stakeholders (e.g. commissioners), resulting in the formation of a specialist task group. Up to 20 follow-up interviews will be carried out.

### 5.3.2 Sampling technique and identification

No sampling will be required for the team workshops or DCC meetings. Purposive sampling will be used to identify potential members of the task groups with the aim of including members from primary, community and secondary care, third sector providers, commissioners and policy makers, as well as people with mild/moderate dementia and family members. Potential members will be identified by the DCC, Alzheimer’s Society, Age UK, the PMB and ESC, local service providers and relevant royal colleges. Additional members will be identified from WS2 participants. The WS2 consent form will include an option to express an interest in taking part in the task groups. Those who express an interest will be considered for participation (using the principles of purposive sampling). Purposive sampling will be used to identify appropriate participants for follow-up interviews; we will aim to include a range of professionals from a variety of services across all sectors.

### 5.4 Approach and recruitment

Co-applicants and researchers will be aware of the team workshops through knowledge of workstream protocols and PMB meetings. The meetings will be arranged by the project administrator and email invitations sent to all team members. Similarly DCC members will be aware of their role in the process of intervention development through their participation in earlier DCC meetings. Additional members may be recruited if required through the Alzheimer’s Society and local contacts. Potential task group members will be approached initially by mail or email; this will provide an overview of the study, the specific role of the task groups and the timescale and location of meetings. They will be followed up by telephone or email after about one week to check whether they wish to take part. The researcher will discuss any video conferencing training needs and whether participants would prefer to take part in an individual telephone interview instead. A similar approach to task groups will be taken for follow-up interviews.

### 5.5 Consent

Formal written consent will be sought from all task group members. Due to the ongoing COVID-19 pandemic, consent processes will be undertaken remotely. Consent forms will be sent to participants along with the invitation and PIS, and a researcher will use the follow up telephone call to answer any questions they may have and to provide guidance on filling out the form. A pre-paid envelope will be provided for returns. Formal, written consent will not be sought from team members or DCC members. Both of these groups have long-term involvement throughout the study (team members in undertaking and critically reviewing the work; DCC members through acting as our mixed stakeholder PPI panel) and will contribute to intervention development as a part of their overall contribution to the study. For follow-up interviews, we will use an electronic version of the consent form and seek a digital signature, rather than written consent.

Consent will be sought to record all meetings. Due to the limitations of the video conferencing software used, both video and audio will be recorded; however, we will delete the video recordings immediately following the meetings and retain only audio. Participants will be fully informed of this prior to joining the meeting. Individual telephone interviews will be audio recorded.

## 5.6 Data collection and management

A member of the research team will be present at all meetings and task groups to take detailed notes and record decisions. Audio-recordings of meetings, task groups and interviews will also be transcribed by an external transcription service (UK Transcription Service) to provide a full reference document which can be used to clarify any areas of uncertainty.

 We will present the components of the intervention identified through WS1, WS2, policy documents and national guidelines to members of the DCC for discussion and validation. We will discuss the relative importance of different components in case some are consistently viewed are more important than others. This information will be provided to intervention sites to inform their decision about which components to adopt locally. Preliminary discussions with the DCC, however, suggest that all components are important and that different components will be more important at certain times and to certain individuals. Trying to prioritise the components is therefore seen as a task to be done at an organisational level, where professionals can consider whether and how the components fit with existing provision, rather than by the DCC. The task groups will then focus on operationalising the agreed components of post diagnostic care. This will include identifying how the components could most usefully be presented for different groups (e.g. care pathway, protocol and manual) and the resources and implementation strategy needed to deliver them.

## 5.7 Data analysis

The evolving nature of the model(s) will be captured through the detailed notes of all meetings (with the transcriptions available as back-up if needed). Details of participants in all meetings and task groups (e.g. role, professional background) will be recorded and summarised. Follow-up interviews will be analysed using similar techniques to those employed in WS2 (see section 4.7).

# 6. STUDY MANAGEMENT

Cumbria, Northumberland, Tyne & Wear NHS Foundation Trust will act as the sponsor for this study. Its role will be to ensure that the study is conducted in accordance with the protocol and to advise the study team on any amendments needed.

# 6.1 Roles and responsibilities of study management committees/groups and individuals

This protocol describes the workstreams 2 and 3 of a larger programme of research. Oversight of the programme, including these workstreams will be provided by the following groups/individuals. A brief summary is given below; the responsibilities and terms of reference for each of the groups are provided in Appendix 2.

6.1.1 Programme Management Board: Professor Louise Robinson, the Chief Investigator (CI) of the programme, will chair the programme management board (PMB) which has responsibility for delivery of the programme and will meet as frequently as needed, minimum 3 monthly.

6.1.2 External Steering Committee: An independent External Steering Committee (ESC), approved by the funders, will provide independent oversight of the programme. The ESC will be chaired by Professor Martin Orrell (Institute of Mental Health, University of Nottingham).

6.1.3 Patient and Public Involvement:Two of the co-applicants (Tucker and Lewins) will be members of the PMB; they have had personal experience of caring for relatives with dementia and are actively involved in the development and conduct of research via the Alzheimer’s Society Patient and Public Involvement (PPI) network.

External PPI programme monitoring will be via a separate Patient and Public Programme Advisory Board (PPAB); this will: oversee progress in terms of milestones/deliverables and act as critical ‘friends’. The PPAB (10-12 people) will be chaired by Ms Sue Tucker (one of our PPI theme leads) and Professor Louise Robinson and will meet once a year. Recruitment will be via our partner PPI organisations (Alzheimer’s Society; Dementia Action Alliance, National Institute for Health Research Dementias and Neurodegeneration Specialty (DeNDRoN) and will ensure that membership is diverse.

Alzheimer’s Society PPI volunteers receive training in basic dementia science, research methods and ethics/governance issues and will also have access to additional e-learning resources as required. Specific training will be provided through two half-day PPAB workshops early in the programme facilitated by our PPI leads. The first will be on the topic of post diagnostic care whilst the second will focus on PPAB responsibilities during the programme and any ongoing support and training desired.

We will additionally establish a Dementia Care Community (DCC) to inform all stages of the programme. The DCC will bring together, from across the UK, people with dementia, and their family members, with a wide range of organisations including service commissioners and service providers (health and social care, Local Authorities, key voluntary organisations such as Alzheimer’s Society, Age UK, Carers UK), together with dementia friendly community initiatives (e.g. Dementia Action Alliance, Comic Relief funded projects).

The DCC will engage in an iterative process of reviewing and refining emerging findings to inform both research conduct and translation into practice. An initial orientation meeting for DCC members linked to WS2 will be held to introduce the programme and explain the role and responsibilities of the team. Subsequent input from the DCC will be sought regularly throughout the programme using a variety of approaches including team meetings; telephone/skype discussions and home visits (particularly for a person with dementia and their family members). Brief summary information would be sent in advance and then explored in more detail through informal face-to-face discussions. We anticipate that each member of the DCC will be contacted up to, but not more than, five times per year to ensure a level of continuity. Meetings will be arranged as needed with a final meeting to review key findings and identify learning points from participants’ experiences.

The DCC will contribute to WS2 through activities such as informing the sample of service managers and commissioners and selection of services for WS2.2; reviewing the good practice models identified; and commenting on their appeal and acceptability.

Since the training and support needs of people with dementia and family members involved in the DCC are not yet known, we will proactively identify training needs and ways of meeting these.

## 6.2 Workstream management

The management of all workstreams will be overseen by the PMB, ESC and PPAB. There will be close liaison between workstreams to ensure that emerging findings are shared at an early stage. This will be achieved through formal meetings and informal contacts (email, telephone discussions). The core team for each workstream (WS leads and researchers) will meet regularly to plan and conduct the work.

# 7. ETHICAL AND REGULATORY CONSIDERATIONS

## 7.1 Assessment and management of risk

Participation involves minimal risk to professional participants. These participants may benefit from the opportunity to reflect on their current service provision and aspects for development. The only cost to participants is the time taken to read study information, complete the consent form and take part in a telephone interview.

This study is low risk to people with dementia and their families. If information was disclosed to the researchers suggesting that the participant or other people were at risk of harm (e.g. suicidal thoughts or disclosure of abuse), the researcher would explain to the participant that we would have to act on this information. This is made explicit in the PIS. The researcher would ensure the immediate safety of the participant (or other person) and then contact the WS leads for advice. If necessary the situation would be discussed with the CI (who is also a GP). The usual course of action would be to discuss the concerns with a professional involved in the person’s care, either their GP or the manager of the service through whom the participant was identified and recruited.

Guardian 24 and the University Lone Working Policy will be used to ensure the safety of researchers.

## 7.2 Research Ethics Committee (REC) and other Regulatory review & reports

The WS leads will obtain a favourable ethical opinion from an NHS Research Ethics Committee (REC) prior to the start of the study. All parties will conduct the study in accordance with this ethical opinion.

The WS leads will notify the REC of all required substantial amendments to the study and those non-substantial amendments that result in a change to study documentation (e.g. protocol or PIS). Substantial amendments that require a REC favourable opinion will not be implemented until this REC favourable opinion is obtained. The WS leads will notify the REC of any serious breaches of good clinical practice (GCP) or the protocol that occur during the study. All correspondence with the REC will be retained in the study master file.

An annual progress report will be submitted each year to the REC by the CI until the end of the study. This report will be submitted within 30 days of the anniversary date on which the original favourable ethical opinion was granted. The CI will notify the REC of the early termination or end of study in accordance with the required timelines. Within one year after the end of the study, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

All researchers will receive training in undertaking research with people with dementia and family members. All staff involved in this workstream will have up to date training in GCP; those with direct contact with people with dementia and family members will complete additional training in assessment of mental capacity, the Mental Capacity Act and informed consent.

Site approvals will be obtained through the HRA and R&D departments of participating NHS Trusts. For non-NHS sites, we will seek approval through social care or from the service manager and their employing organisation as appropriate.

The Sponsor will determine if an amendment is substantial or not and study procedures will not be changed without the mutual agreement of the CI and Sponsor. Substantial amendments will be submitted to the REC and will not be implemented until the relevant approval is in place. The appropriate workstream team will submit substantial amendments on behalf of the CI. Non-substantial amendments may be made at any time with a record of the amendment held in the Study Master File. Any non-substantial amendment that requires an update to the study documentation will be submitted to the NHS REC for acknowledgement of the revised version of the document. Substantial amendments and those minor amendments which may impact sites will be submitted to the HRA for notification to determine if the amendment affects the NHS permission for that site. Amendment documentation will be provided to sites by the appropriate workstream team.

## 7.3 Regulatory Review & Compliance

The programme grant, including this work stream, underwent two rounds of extensive peer review by the study funder.

All parties will conduct the study in accordance with the protocol. The WS leads will notify the sponsor of any required amendments to the study The WS leads will notify the sponsor of any serious breaches of GCP or the protocol that occur during the study. All researchers will complete up to date training in GCP and informed consent.

A final report will be submitted to the sponsor by the WS leads on completion of each WS. The WS leads will notify the sponsor of the early termination or end of study in accordance with the required timelines.

## 7.4 Data protection and confidentiality

Personal data will be regarded as strictly confidential. A Participant Identification Log will be the only document which contains full details of participant name and study ID. This is essential to enable participants to be contacted regarding study participation. The Participant Identification Log will be stored on a University networked computer and will be password protected. The only personnel with access to the log will be study administrative staff and those research staff directly involved in data collection. Completed study documentation will be stored in locked filing cabinets on University premises which are accessible only by smartcard. Transcripts and fieldnotes will be anonymised by members of the team involved in data collection; other team members will only have access to anonymised data.

The CI will be the custodian of the data. Data will be stored for 5 years following completion of the study in a secure archive and then destroyed.

The study will comply with the General Data Protection Regulation (GDPR). All study records will be kept in a locked filing cabinet in University offices which are accessible only by smartcard.

## 7.5 Protocol compliance

Accidental protocol deviations will be documented and reported to the CI and Sponsor immediately. Any deviations which occur on more than three occasions will be investigated by the WS leads to understand the underlying reasons and identify how best to prevent further breaches. The deviations and actions to be taken will be documented and reported to the CI and Sponsor. An audit of consent forms will take place after the first ten recruits to check for any problems and identify additional training needs. If required, a further audit will take place after the next ten recruits.

## 7.6 Indemnity

Cumbria, Northumberland Tyne and Wear NHS Foundation Trust is Sponsor and through the Sponsor, NHS indemnity is provided in respect of potential liability and negligent harm arising from the conduct of the study.

Indemnity in respect of potential liability arising from negligent harm related to study design is provided by NHS schemes for those protocol authors who have their substantive contracts of employment with the NHS and by Newcastle University Insurance schemes for those protocol authors who have their substantive contract of employment with the University. This is a non-commercial study and there are no arrangements for non-negligent compensation.

No payment will be given to individual participants for taking part in the study. A small payment will be offered to services participating in WS2.2 in recognition of the time they have given to the project.

## 7.7 Access to the final study dataset

In line with the recommendations by the International Committee of Medical Journal Editors (ICMJE), access to the final, cleaned, anonymised dataset will be available within 12 months of publication in a print, peer-review journal. The PIS will contain a statement to this effect, and the informed consent form will invite participants to consent to their anonymised data being shared as part of the final dataset.

The final anonymised dataset will be stored in a repository that conforms to the General Data Protection Regulation (GDPR) and subsequent legislation. Requests to use the dataset for secondary analyses will be authorised by the PMB if the study is ongoing or by a data review committee established following the end of the study. Written confirmation that data use will conform to current legal, ethical and regulatory frameworks will be necessary. Data access request forms will require authors of secondary analyses to agree to the following:

* Attest that their use of the data was in accordance with the written terms of agreement for use
* Data supporting a publication should be in a citeable form, using a unique identifier for the PriDem programme
* Explain how their analyses differ to the original PriDem publications
* Credit, preferably by collaboration, those researchers who generated the original dataset.

# 8. DISSEMINATION POLICY

## 8.1 Dissemination policy

The CI will be the custodian of the data. On completion of WSs 2 and 3 reports will be produced summarising the main findings and summaries will be disseminated to study participants. The findings will also be reported in a peer-reviewed journal and presented at national and international conferences (either as stand-alone findings from each WS or integrated with findings from other WS).

The programme as a whole has a dedicated workstream relating to dissemination and translational strategy. We will utilise, and integrate with existing dissemination networks and programmes, e.g. national and regional conferences, websites and newsletters. In addition, PriDem programme-specific activities will also include: a study website, social media, newsletters and information resources for people with dementia, their families and care providers.

For the programme as a whole, we will also hold two national dissemination events, targeting different audiences including i) people with dementia and their families; ii) policy makers and service commissioners and iii) service providers. For each key group, we will identify their main dissemination networks and communication channels including social media, and specifically address individual group requirements in terms of how we succinctly convey the key, tailored findings of our research and their implications. For group iii), the research team will aim to produce materials that meet needs for continuing professional development and will provide practice-relevant material in the professional press as well as more traditional research outputs.

## 8.2 Authorship eligibility guidelines

A publication policy for the programme has been drafted and is currently under review by the PMB.

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# APPENDICES

## Appendix 1 Security and confidentiality agreement for transcription company

**Confidentiality & Non­-Disclosure Agreement ­ Client**

**This Agreement is made on the <*insert* date> between**

**UK Transcription Ltd of 15-17 Middle Street, Brighton, BN1 1AL (“UKT”)**

**and**

**PriDem team, Institute of Health & Society, Newcastle University (“The Client”).**

UKT has been appointed by the Client to transcribe video/audio files and documentation (“Work”) which will involve the disclosure to UKT of sensitive and confidential data relating to both the Client and/or its client(s).

* In consideration of payment by the Client for work, UKT undertakes to:
* maintain confidentiality and not to disclose to any person or organisation other than the Company (save as required by law) at any time any work including but not limited to any and all audiotapes, videotapes, and oral or written documentation provided by the Client to UKT.
* not use any confidential information for any purpose except to evaluate and engage in the performance of transcription services for the Client;
* not authorise or otherwise enable any other person or organisation to have access to the content of work (save as required by law) without obtaining the Client’s prior written consent;
* take all necessary steps to secure data in relation to work with encryption and to permanently destroy the same after use with a file shredder or other effective method;
* not make any kind of contact with and/or solicit business from any person or organisation involved (directly or indirectly) with work provided by the Client.
* For the avoidance of doubt, the undertakings set out in clause 1 above shall apply both during the period in which work is carried out and at all times thereafter;
* Neither the Client nor UKT intend to create the relationship of employer and employee between them and nothing in this Agreement shall comprise such relationship. Accordingly, UKT shall be solely responsible for any tax and other responsibilities arising out of performing and delivering work pursuant to this Agreement,

This Agreement shall be governed by and construed in accordance with the laws of England and the parties hereby submit to the exclusive jurisdiction of the English courts.

Signed by ………………………..

For and on behalf of the Client Date ………..……………….

Signed by: …………………………..

For and on behalf of UKT, UK Transcription Ltd Date: ………………

# Appendix 2 Programme management structures

### Internal management and monitoring

**Terms of reference for all management bodies (PMB, ESC, DCC, PPAB)**

### Programme Management Board (PMB) Terms of reference

Day to day management of the PriDem programme will be overseen by the PriDem PMB, chaired by the programme PI (Robinson) and comprising of all other co-applicants from the PriDem bid. The PMB will meet regularly (between 4-8 weeks) either face to face or via teleconference.

The PriDem PMB terms of reference and responsibilities will be as follows:

1. To undertake day to day management of PriDem, and the PriDem staff, at the host institutions.
2. To oversee and ensure ethical and appropriate governance approvals are in place.
3. To oversee financial management and accountability.
4. To oversee recruitment, training and support of programme staff where possible.
5. To ensure all milestones are being met and to monitor and supervise the progress of these.
6. To discuss confidentially any issues raised during the PriDem programme, or from external monitoring groups, and work towards a solution as quickly and effectively as possible.
7. To be responsible for ensuring timely and accurate reporting of PriDem related research and finance reports.
8. To contribute as required to dissemination activities and to production of reports, and other outputs, required by the funder and other external bodies to evidence the achievements of PriDem.
9. To represent the PriDem programme at funder (Alzheimer’s Society) meetings and other strategic events.

### External Steering Committee (ESC) Terms of reference: Roles and responsibilities

The roles and responsibilities of the PriDem ESC are to:

* Provide expert advice during the conduct of a programme that is independent of the Investigators
* Supervise the overall programme, on behalf of the funder (Alzheimer’s Society) and the sponsor. The day to day management of the programme is the responsibility of the Chief Investigator and co-investigators and management structures, such as programme management groups; these internal structures will report to ESC on overall progress
* Meet at least annually and more frequently if judged necessary – at the request of the Chief Investigator however the funder or the sponsor have the right to convene a meeting in exceptional circumstances
* Monitor progress against pre-agreed milestones (such as recruitment and follow-up rates), adherence to the agreed programme and any measures of patient safety. It is the responsibility of the Chief Investigator to bring all relevant information to the attention of the ESC and, responsibility shall reside with the ESCs independent Chair to approve/sign off annual progress reports submitted to the funder
* Provide advice to the Investigators, the Programme funder, the research sponsor, the host institution, and the contractor on appropriate aspects of the programme. Serious concerns or disagreements should be brought to the urgent attention of the Programme funder, and to other parties as appropriate
* Decide whether a further independent Data Monitoring Committee (DMC) is needed for any aspects of the programme, such as randomised controlled trials; if so, to liaise with the Programme funder to suggest and agree membership and subsequently to receive any reports from the DMC and act on any advice
* Provide written evidence to support any requests for additional funding or time extensions, indicating that all practical steps have been taken by the investigators to achieve targets and/or that changes to the planned work are fully justified
* Encourage appropriate efforts to disseminate the programme’s findings, including through timely provision of the final report, publications and other forms of dissemination.

### The Role of the Chair of ESC

The Chair of the ESC is directly answerable to the Programme funder. The Chair’s responsibilities include:

* Establishing clear reporting lines to the Funder, Sponsor and other key stakeholders
* Approve/sign off annual progress reports submitted to the Programme funder
* Being familiar with relevant guidance documents and with the role of the DM(E)C
* Providing an independent, experienced opinion if conflicts arise between the needs of the research team, the funder, the sponsor, the participating organisations and/or any other agencies
* Leading the ESC to provide regular, impartial oversight of the programme, especially to identify and pre-empt problems
* Being available to provide independent advice as required, not just when ESC meetings are scheduled
* Commenting on any extension requests and, where appropriate, providing a letter of recommendation to accompany such a request
* Commenting in detail (when appropriate) regarding the continuation or termination of the project.

### Dementia Care Community (DCC) Terms of reference: Roles and responsibilities

The DCC will bring together a group of individuals all of whom have experience of either living with dementia or working with individuals with dementia and their families. By drawing on this individual and collective experience, we hope to ensure that the programme of work is embedded in real life experiences and is tailored to local contexts. Consequently the membership of our PriDem DCC will need to be flexible, and responsive to the needs of the research programme and the different workstreams. Thus participants for the DCC will be recruited from different locations; this will enable local groups to meet more easily and work closely with specific workstreams. Participants can contribute to the DCC in a variety of ways including via email; skype; attending meetings; or having home visits by a member of the research team.

The roles and responsibilities of the PriDem DCC are to:

* Provide alternative experience-based perspectives to the project team and posed research, either as a person living with dementia, a family member or a professional delivering services to people with dementia
* Offer feedback on proposed recruitment approaches and materials
* Discuss any problems encountered in delivering the programme and suggest strategies to address these
* Provide feedback on data collection tools, such as topic guide
* Contribute to the development of new model(s) of post diagnostic care through activities such as:
	+ Identifying key outcomes
	+ Identifying key components of the intervention
	+ Considering practical aspects of intervention delivery (when, how, who, where, how often)
* Contribute to raising awareness of programme staff by sharing experiences of living with dementia and/or service delivery
* Develop user-friendly versions of programme outputs such as presentations, papers
* Advise on appropriate ways of publicising and disseminating the programme and its outputs (e.g. through newsletters and a programme website)

Overall the DCC will be co-ordinated by the PI (Robinson) and workstream 2 co-lead (Bamford) with local management led by individual workstream leads. At a local level, the DCC will be convened by members of the research team, who will:

* Liaise with members to identify their preferences for taking part
* Maintain regular contact and keep members updated (frequency to be agreed by DCC members)
* Encourage feedback and reflection on the format and content of the DCC so that it can be adapted as needed
* Ensure feedback from the DCC is fed back to the wider programme management team

**The research team will ensure the following:**

* Research questions, methodology, analysis and findings are explained and summarised in a clear, jargon-free and concise manner
* Information will be written in an accessible format
* Members of the group will be kept up to date with progress of the research and provided with summary documents if possible
* Members’ views and suggestions will be valued.

### External PPI Advisory Board (PPAB)

**What is the purpose of the Advisory Board?**

The PPAB has been designed to support communication and input from the public. The PPAB will provide representation and so in turn essential feedback from people with dementia, and their families, on the research programme. This will provide a dual function of facilitating the progress of individual projects within their ‘day to day’ environments, and more importantly providing comment and advice on the feasibility and implementation of the intervention the programme is ‘testing out’.

More specifically the PPAB provides an opportunity for people with varied experience of living with dementia to contribute to and influence our research through:

* Bringing together the views and opinions of people with different experiences of dementia.
* Offering advice on the proposed research methods utilising the experiences of people living with dementia.
* Provide comment on any findings and outputs, and making suggestions about the dissemination of the research and how best to influence practise.
* Exchanging ideas and information while ensuring the confidentiality of the research and any other information shared within the group.
* Highlighting and advocating any issues that people may identify that relate to gender, ethnicity, culture, sexual orientation or age.

***The research team will ensure the following:***

* Research questions, methodology, analysis and findings are explained and summarised in a clear, jargon-free and concise manner
* Information will be written in an accessible format
* Members of the group will be kept up to date with progress of the research and provided with summary documents if possible
* Members’ views and suggestions will be valued

**Location**

All PPAB meetings will be held at either Newcastle University or University College London.

**How often?**

* Yearly over 4 year programme
* Booked six months in advance
* Each meeting to last an agreed length of time, minimum 3 hours
* Expenses will be met and a fee is payable to unwaged members

**Chair/Lead**

* Louise Robinson
* Sue Tucker