Project Protocol
Short title: Developing an Intervention for Fall Related Injuries in Dementia (DIFRID)

Full title: Is it possible to develop a complex intervention to improve the outcome of fall-related injuries in people with dementia?

Glossary of Abbreviations:

AD	Alzheimer's disease
ADL	Activities of daily living
CCG	Clinical Commissioning Group
COMET	Core Outcome Measures in Effectiveness Trials
CTA	Clinical Trials Assistant
DeNDroN	Dementia and Neurodegenerative Diseases
DLB	Dementia with Lewy bodies
ED	Emergency department
FNOF	Fractured neck of femur
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HRQoL	heath related quality of life
ICD	International Classification of diseases
NGT-R	Nominal Group Technique- RAND Corporation
NPT	Normalisation process theory
PMG	Project management group
PPI	Patient and public involvement
ProFaNE	Prevention of Falls Network Europe
PWD	person or people with dementia
QOF	Quality Outcomes framework
RA	Research Associate
RAMSES	Realist And Meta-narrative Evidence Syntheses: Evolving Standards
RCT	Randomised controlled trial
VAD	Vascular dementia
WP	Work package

Summary of Research:

Fall related injuries are a significant cause of morbidity and mortality in people with dementia (PWD). There is presently little evidence to guide the management of such injuries, and yet there are potentially substantial benefits to be gained if the outcome of these injuries could be improved. This 26 month study aims to provide the evidence needed for the design of an appropriate healthcare intervention for such PWD and to assess the feasibility of its delivery in the clinical setting.

Work Package 1: Systematic Literature review
Strategy for reviewing literature: review of bibliographic source, existing investigator reference databases, grey literature and key references as identified from experts in the field to identify studies examining: the health and social care needs of PWD with fall related injuries, outcomes of importance to patients/carers and evidence on the relative effectiveness of interventions. Methods of systematic review of effectiveness will be based upon those of the Cochrane Collaboration and realist synthesis.

Work package 2: Understanding current practice and describing current usual care
Design: prospective observational study over 6 months with qualitative study

Settings: 3 UK sites (Newcastle, Stockton, Norwich) each including 3 settings: primary care consultations, paramedic attendances and Emergency department (ED) attendances.

Target population: PWD presenting with fall related injuries in each setting at each site.

Health technology assessed: Procedure for ascertaining person has a diagnosis of dementia, estimation of number of PWD presenting in each setting, identification of services they are directed to after the fall. In each site a subgroup of 20 PWD and their carers will keep a diary of service usage for 3 months, to describe the type and quantity of care accessed and care pathways followed by such individuals. Qualitative interviews to explore their perceptions of what their care needs were, whether they were met, what might have been improved and what outcomes were important to them. Qualitative interviews of care professionals they encounter, to identify their perceptions of the health and social care needs of PWD, ideas for service improvement, barriers and facilitators to change.

Work package 3: Intervention development and validation
Design: Convening of an expert panel with qualitative study

Health technology assessed: the panel will review the results of WP1 and 2; assess the feasibility and appropriate setting for recruiting participants to receive the intervention, assess and prioritise specific elements to be combined in a complex health care intervention, identify the most appropriate setting and professionals required for delivery of the intervention, training needs, identify and prioritise outcomes to be measured. Qualitative study: exploration of acceptability of proposed intervention with a range of stakeholders including those identified in WP2.

Work package 4: Pilot implementation
Design: Rehearsal of intervention with process evaluation

Settings: as WP2

Target population: 15 PWD with a fall related injury in each site (total 45)

Health technology assessed: feasibility of participant recruitment, fidelity of delivery of the intervention, feasibility of outcome measurement. Qualitative study: assessment using normalisation process theory of factors influencing the acceptability and implementation of the intervention.

Final output: Description of a validated complex intervention with accompanying training materials for its delivery and measurement of outcomes.

Background and Rationale:

It is estimated that in 2011 670,000 people were living with dementia in the UK, of whom 70% live in their own homes, often receiving extensive support from family carers[2]. Although the prevalence of dementia is decreasing among older people, the ageing population means that the absolute numbers of PWD will continue to rise. In our previous study the annual prevalence of falls in PWD ranged from 47-90%, depending on dementia subtype, and PWD living in their own home sustained almost 10 times more incident falls than controls, and their falls were more likely to be injurious[1]. PWD are less likely to recover well after a fall, more likely to be hospitalised, are hospitalised for longer and are more likely to require increased care[3].

There is little evidence regarding the care pathways currently experienced by PWD presenting with a fall related injury, although it is known that falls are a common reason for admission in PWD[4], and that most admissions in PWD with an injury are due to a fall[5]. PWD may present to health services in a range of ways after an injurious fall; the most likely being presentation to emergency services, either via the ambulance service or directly to the Emergency Department (ED). In all cases the health care received after such a presentation will be driven initially by the type and severity of the injury and any medical condition which has directly led to the fall; for example an injury may be managed conservatively, or with a minor or major procedure. Although most falls resulting in a fracture will usually lead to the person presenting to the ED, we know from our previous study of risk factors for falls that the majority of injuries sustained are only soft tissue injuries[1]. We found that the annual incidence of soft tissue injuries ranged from 2.5 times greater in Alzheimer's disease (AD), than in controls, to 11 times greater in Parkinson's disease dementia (PDD) (unpublished data). Some with less urgent injuries may present directly to primary care. Paramedics or GPs seeing older people with only soft tissue injury are usually less likely to refer the person to hospital, but other factors may nevertheless lead to admission and a third of PWD admitted with an injury do not have a fracture[5]. Comorbid factors are more likely to be present in PWD [6] and include an underlying acute medical cause of the fall, delirium, inability to mobilise and carer stress or lack of ability to support them after the fall.

Up to 40% of people presenting to the ED will have a cognitive disorder [7] and this has been shown to be a barrier to providing good emergency care, and may result in preventable admission. A recent review has shown that the evidence underpinning management of PWD in the ED reflects expert opinion rather than controlled trials[7]. PWD presenting to the ED are therefore currently managed using services not designed to meet their needs: a successful intervention would improve care in the ED and may reduce hospital admissions.

Some injuries cause unavoidable admissions, such as fractured neck of femur (FNOF). If admission is required, some technical elements of procedures required to ameliorate an injury would not necessarily be influenced by the presence of a dementia diagnosis, e.g. the choice of hip screw in the case of a fractured hip, but the processes surrounding delivery of such treatment do need to take account of the impact

of dementia and there is a paucity of tools to assess PWD admitted with FNOF[8]. Many hospitals now have generic care pathways to support inpatient PWD, but families are frequently dissatisfied with general hospital care[9]. There are no current pathways specific to fall related injury in PWD. Staff often perceive PWD as less capable of rehabilitation due to lack of person centred supportive strategies[10]. If supportive care needs are identified for discharge, a range of community services may be accessed, but staff in these services may not have specific training in the care of PWD.

There is a range of ways in which improved management of fall related injuries might reduce adverse sequelae for PWD and carers. Firstly, any fall in older person, whether injurious or not, is known frequently to result in fear of falling and psychological morbidity which may lead the person to restrict their mobility, which result in deconditioning and a cycle of further loss of mobility and frailty. A successful intervention may reduce psychological morbidity and improve wellbeing[11].

Secondly, if physical recovery from the injury itself is poor, further restriction of mobility may occur and independence in activities of daily living may decline. These restrictions may result in reduced social participation, increased burden for informal carer and increased need for formal care. Such problems lead to reduced wellbeing and quality of life for PWD, and substantial costs to both health and social care systems. A successful intervention may support the maintenance or reduce the degree of physical decline and loss of independence. We are not aware of any clinical trials which have specifically tried to address the management of all fall-related injuries in PWD, but there is one small trial showing benefit from a multidisciplinary intervention in a subgroup of people with FNOF who had dementia [12]and there is an ongoing trial of a patient centred model of rehabilitation in people with FNOF and cognitive impairment[13]. In addition one of the investigators is currently Principal Investigator of a NIHR funded programme: Peri-operative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-"PERFECTED". The aims of this programme overlap with the present research question in that they focus on a specific type of fall related injury in PWD, but there remains a need to improve management of non-FNOF fall related injuries in PWD.

After immediate management of an injury and any underlying medical emergency, much of the health care required will not be directly related to the injury itself, but will need to focus upon prevention of physical and psychological complications, recovery of function, prevention of disability, social support, carer support and prevention of further falls. For older people without dementia there is good evidence that a multifactorial intervention by a specialist falls service will prevent further falls[14, 15]. The components of such a multifactorial intervention are usually directed at known risk factors for falls identified in the individual receiving the intervention. However, such multifactorial interventions have not been shown to be consistently effective in dementia[16] and indeed there are trials which have shown no benefit[17, 18]. It is possible that this is because risk factors for falls may differ in PWD or be more frequent or specific to dementia; e.g. wandering [19]or behavioural disturbance[20], Parkinsonism[21, 22], severity of cognitive impairment[21] functional impairment[23] and neuroleptics[24, 25]. Nevertheless, and despite the lack of evidence, for those whose injury or underlying medical condition does not require urgent assessment in hospital, GPs and paramedics often make a referral directly to the local falls service, irrespective of dementia. Such services are not usually tailored to meet the needs of PWD. It is possible that the referral may achieve other benefits for the PWD, such as medication review, treatment of other comorbidities or provision of aids to support activities of daily living, but it is not known whether a falls service is the best setting for addressing these goals. Indeed it is not known what goals would be of most importance to PWD who fall. In designing any kind of intervention to address the problem of fall related injuries in PWD, it is vital that the intervention addresses outcomes of importance to PWD themselves, their carers and their care professionals. We accessed the COMET initiative database and found no consensus regarding suitable outcomes for fall related injury, although there were two publications regarding interventions of relevance in this situation: the ProFaNE Consensus on a common outcome data set for fall injury prevention trials[26] (domains include falls, injuries, psychological consequences of falling, HRQoL, physical activity) and those identified by the European Consensus on outcome measures for psychosocial intervention research in dementia care[27] (domains include patient mood, quality of life, activities of daily living and behaviour, and carer mood and carer burden).

In summary PWD, who sustain fall related injuries currently receive a range of health interventions, but a single model of care for this specific situation has not previously been described and the potential demand for such an intervention is not known. Given all the aspects of care relevant to the situation as described above it is apparent that a new model of care would take the form of a complex intervention. Given the frequency of this problem in PWD it is clear that this is an important area for research. There is also no current consensus on the best outcomes to measure the impact of such an intervention or its cost effectiveness and therefore research is required to develop suitable outcomes.

Aims and objectives:

The overall aim of this study is to assess through a series of work packages (WPs) whether it is possible to design a complex intervention to improve the outcome of fall-related injuries in people with dementia living in their own homes.

Work Package 1: Literature review

To conduct systematic literature reviews which will synthesise the current evidence regarding the management of fall related injuries in dementia:

a) What are the health and social care needs of community dwelling people with dementia (PWD) sustaining a fall related injury?

b) Which outcomes are important and relevant for such PWD, their carers and their health and social care professionals (the stakeholders)?

c) What evidence is currently available regarding the effectiveness and cost effectiveness of interventions aimed at improving the outcome of fall related injuries in PWD?

Work package 2: Understanding current practice

To explore how PWD are currently presenting to healthcare services with a fall related injury, across a range of UK settings, and to assess their needs and relevant outcomes:

a) To quantify in 3 UK sites, PWD presenting to health services with a fall related injury. In each site numbers of cases and availability of diagnoses will be measured in 3 settings which might be suitable for identifying recipients of an intervention: primary care consultations by PWD, paramedic attendances at homes of PWD and attendances at the emergency department (ED) by PWD (total 9 settings)

b) To understand current care pathways ("usual care") experienced by a subgroup of PWD identified in WP 2a), and to assess what services PWD who experience a fall use and use these data to develop a data collection tool for use in the evaluation of a new intervention

c) Through a qualitative study with a subgroup in each site, to identify their care needs, to explore the opportunities for and the barriers to improvement in their care from the perspective of all stakeholders and to identify and prioritise the outcomes which are important to the stakeholders

Work package 3: Intervention development and validation

To develop and validate an intervention to improve outcomes for PWD with a fall related injury, drawing on the findings of WP 1 and 2:

a) Convening an expert panel to

-Review the results of the WP1 and 2 in order to identify the key elements to be included in the intervention, the most appropriate setting for recruiting recipients of the intervention, where it should be delivered and its feasibility within UK NHS practice settings

-Describe the outcome measures to evaluate the effectiveness and cost-effectiveness of the intervention

b) To validate the proposed intervention through qualitative work with stakeholders, including some participants from WP2.

Work package 4: Pilot implementation of intervention

In a non-randomised feasibility study, to deliver the proposed intervention to 15 patients in each of the 3 sites, and to assess

a) Is it possible to recruit PWD to such a study?
b) Can the intervention be delivered in the proposed setting in each of the 3 sites?
c) Is it possible to collect relevant outcome data?
d) Through a qualitative study, to understand factors influencing the acceptability and implementation of the intervention

Research Plan:

This study will use a range of designs and methodologies to answer the research questions over the course of 4 linked WPs in accordance with the MRC guidance on the stages of developing and evaluating complex interventions.

Overview of the health technology being assessed:

The health technology to be assessed in this project is a complex intervention and is at the earliest stage of development described in the MRC guidance on developing and evaluating complex interventions. People with dementia who sustain fall related injuries currently receive a range of health interventions, but a single model of care in the form of a complex intervention for this specific situation has not previously been described and the potential demand for such an intervention is not known. We have taken the approach that in order to develop a new, person centred and effective complex intervention for this group of patients, we must first be able to answer the following **research questions**.

1. What are the health and social care needs of patients and carers which must be addressed by the complex intervention?
2. What is the likely demand for the complex intervention?
3. What are the health and social care interventions already being received by patients and carers (i.e. what is usual care)?
4. What are the best available ideas for a new complex intervention (from the perspectives of all stakeholders)?
5. What are the outcomes of importance which the complex intervention must influence (from the perspectives of all stakeholders)?
6. How should changes in these outcomes be measured with respect to clinical effectiveness and cost-effectiveness and have these been measured in any previous studies?

In **WP 1** we will identify existing literature which addresses these questions. We anticipate that the literature in this area will be scarce; therefore, **WP 2** will provide additional primary research evidence to answer these questions from the perspectives of all stakeholders (patients, carers, health and social care professionals and health and social care commissioners). This will provide us with the best available evidence and theory required to design an appropriate new complex intervention.

In **WP 3** we will convene a professional and PPI consensus panel to review the findings of the prior work packages. A modified Delphi approach will be used to ensure the design of the new intervention takes account of the full range of stakeholders' views and not just the views of the research team. Given the necessity for the preceding research which will inform the design of the complex intervention in WP 3, it is not possible to describe the intervention in detail at this point. However, from our initial review of the literature and our knowledge of previous research in both falls in older people, and in the generic care of PWD, it is possible to deduce that the panel may describe a range of interventions, which may vary considerably in intensity. The lowest intensity intervention would be an educational

intervention. In this case, the usual multidisciplinary staff in the usual settings would deliver care, but staff would receive additional training in the principles of dementia care. A medium intensity intervention might include usual multidisciplinary professionals delivering the majority of care, after receipt of an educational intervention and with consultative input from a dementia specialist. In a high intensity intervention, a multidisciplinary specialist dementia team might deliver all the care, in a dementia friendly environment. The team might provide elements of a falls service, but also provide expertise such as antipsychotic review or management of challenging behaviour.

Once a new intervention is designed it needs to be assessed in a phased approach, via pilot studies which explore the feasibility of implementation and address any uncertainties in design. In **WP 4** we will undertake a rehearsal of the intervention in a pilot study. We will assess the feasibility of participant recruitment to a clinical trial of the health intervention, assess the fidelity of delivery of the intervention in an NHS setting, assess variability of delivery between sites and assess the feasibility of outcome measurement. In a qualitative study we will assess the factors influencing the acceptability and implementation of the intervention. The evidence from WP 4 will be used to make recommendations regarding whether it is feasible to deliver the intervention designed in WP3 in an NHS setting, and any necessary changes in the design of the intervention which would be required before planning a definitive clinical trial to evaluate the effectiveness and cost effectiveness of the intervention. We describe the WPs in detail below:

Work package 1

Design and theoretical/conceptual framework:

We will use established methods of systematic review to identify empirical evidence regarding the health and social care needs of PWD with fall related injuries, outcomes of importance to patients, carers and professionals and comparative studies providing evidence on the relative effectiveness and cost effectiveness of interventions. Methods of systematic review will be based upon those of the Cochrane Collaboration. The systematic reviews in WP1 will be registered on the PROSPERO database of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/) and progress will be reported on the website. As we expect the number of articles eligible to be included in the systematic review to be scarce, the review will be supplemented using the methodology of realist synthesis. This more recent approach to the review and synthesis of evidence will enable us to include qualitative studies and focus on understanding the mechanisms by which putative complex interventions might work to improve outcomes for our target population. We will adhere to methodological guidance developed by the Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMSES) project (http://www.ramsesproject.org). The synthesis will assist the panel in WP3 in their evaluation of all possible ideas regarding the components to be included in the newly designed intervention.

Target population:

For the Cochrane review, articles will be included if they include people with a known diagnosis of dementia who live in the community, and who present to health services having sustained a fall with or without related injury.

For the realist synthesis, we expect that we may need to examine literature from related populations in order to ensure that we access the full range of potential ideas for components of the intervention. Articles relating to PWD with non-injurious falls will be included because they do include a very similar population to the target population of the brief. If literature is very sparse with respect to ideas for interventions, we will also consider evidence from non-cognitively impaired older people with fall related injuries.

Search strategy:

The searches for the systematic review and the full scope of the realist synthesis will be performed will be agreed by investigator consensus in consultation with the PPI panel. We will review bibliographic sources, existing investigator reference databases, grey literature and key references as identified from experts in the field. Databases reviewed will include AMED, CINAHL, MEDLINE, EMBASE, Cochrane Libraries, Biomed Central, Health Management Information Consortium, Physiotherapy Evidence Database (PEDro), Zetoc and the NHS Economic Evaluation Database. Unpublished literature and clinical trial registries reviewed will include: OpenGrey, WHO International Clinical Trials Registry Platform, Current Controlled Trials, UKCRN Portfolio Database, National Technical Information Service and the UK National Research Register Archive. NHS sources will include the DH Publications site, and the NHS's NICE recommendation database.

Eligible literature will include both quantitative and qualitative studies which examine the presentation rates and care pathways experienced by PWD who sustain a fall related injury, studies which seek to identify the health and social care needs of PWD who fall, studies which seek to identify relevant health and social care outcomes in this group and studies which examine the effectiveness of interventions relevant to the management of fall related injuries within a clinical trial. Finally we will identify current methods for evaluating quality of life in the target population. A generic heath related quality of life (HRQoL) may not be appropriate for this study and so we will examine both other dementia specific quality of life measures and those measures previously used in the falls literature. We will identify appropriate quality of life measures that can capture the performance of the intervention and present these to the panel in WP3 for consideration.

Data collection:

A database of published and unpublished literature will be assembled. Citations will be selected for inclusion using criteria based on the research questions above. Copies of full manuscripts of potential articles will be obtained and two reviewers will independently select those which meet the predefined criteria. Data will be extracted using a bespoke data extraction form which extracts the information

required for both reviews. Authors of conference abstracts will be contacted for full papers if available and included articles will be tracked in Science Citation Index to identify further relevant articles. New articles meeting our search terms will be identified during the period of the review using electronic alerts.

Data analysis:

Quality of included studies will be assessed using accepted standards for systematic review: Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology and Newcastle Ottawa scale for non-randomised studies. Meta-analyses will be performed using standard software if sufficient literature is available. Heterogeneity of results will be assessed statistically and graphically using funnel plots, and sub group analyses will be used to explore sources of heterogeneity. The realist synthesis will cover the papers identified in the systematic review and qualitative or mixed method studies linked to these papers, as well as papers exploring our research questions in the extended populations described above. Themes will be identified with respect to ideas for components of an intervention and ideas for relevant outcomes. For each theme we will consider the interactions between context, mechanisms and outcomes. The findings of each review will be joined using narrative text and commentary for consideration by the panel in WP3; these will be sent to the panel for review in advance of the first meeting.

Work package 2:

Health technologies being assessed:

We anticipate that the literature addressing our research questions in WP1 will be scarce; therefore, WP2 will provide additional primary research evidence to answer these questions from the perspectives of all stakeholders (patients, carers, health and social care professionals, health and social care commissioners). This will provide us with the best available evidence and theory required to design an appropriate new complex intervention.

Design and theoretical/conceptual framework:

We will use both quantitative and qualitative methods in an observational study, which will describe current models of usual care and identify how the models might be adapted in a complex intervention package.

a) A prospective design will be used to quantify in 3 UK sites, the numbers of incident PWD presenting to health services with a fall related injury, and to determine how many present to each of 3 settings: primary care consultations, paramedic attendances and attendances at the emergency department (ED) (total 9 settings). The proportion in whom a known diagnosis of dementia can be verified by the research team will be determined.

b) A combination of quantitative and qualitative methods will be used to describe and understand current care pathways ("usual care") experienced by a subgroup of 20 participants (PWD and carers). We will make use of prospective diary completion to identify the range of services accessed by the participants. We will quantify the frequencies with which different service elements are accessed, which health and social care professionals are delivering the care and for how long. This will allow us to describe the pattern of usual care with which any intervention will be compared in the future. The information acquired in the diaries will also be used to assess resource use by the participants and to enable the development of a health economic tool to measure the use of services in a definitive study.

c) A qualitative study of patients and carers from the sub study and of health and social care staff providing or commissioning their care will be undertaken in each site, using semi-structured interviews. This will identify care needs; explore the opportunities for and the barriers to improvement in their care from the perspective of all stakeholders; and identify and prioritise the outcomes which are important to different stakeholders. Additionally we will explore the extent to which existing falls interventions at each site (e.g. exercise classes; falls clinics) are appropriate for PWD through observation. Data collection and analysis will be informed by Normalization Process Theory which will enable us to develop a theoretical understanding of the likely processes of change required to improve the current model of care.

Target population:

People with a known diagnosis of dementia who live in the community, and who present to health services having sustained a fall related injury. The definitions of "known diagnosis of dementia" and "fall related injury" are given in the inclusion criteria below.

Inclusion/Exclusion Criteria:

Inclusion criteria

Participants will be adults with a known diagnosis of dementia, made prior to entry into the study, by a specialist in dementia care (Geriatrician, Neurologist or Old Age Psychiatrist). The diagnosis must be confirmed within 72 hours by the patient's GP who will be asked to confirm that the potential participant is on the practice's QOF register of people with dementia, or the GP will confirm that the person's records contain confirmed Read Codes which will result in the QOF register being updated to include this person. Appropriate Read Codes (and their equivalent ICD codes) for including a person on the QOF register are given in appendix 1.

Participants must have sustained at least one fall related injury within the 48 hours prior to their identification as a potential study participant. The fall causing this injury will be known as the ***index fall***. A fall will be defined as defined as an event whereby a person comes to lie on the ground or another lower level with or without loss of consciousness. Injuries will be defined using ICD-10-CM Diagnosis Codes: "Injury, poisoning and certain other consequences of external causes S00-T88". A fall related injury will be defined as an injury which comes about as a direct consequence of the index fall.

Participants must be dwelling in the community at the time of the index fall.

For those participants who will complete the sub study, there will be an additional requirement that the person must have a family member or other carer available to assist with completion of the diaries.

Exclusion criteria

Participants will be excluded from the study if the diagnosis of dementia cannot be confirmed by consultation with the GP within 72 hours of their being identified as a potential participant, or if it is found that they were dwelling in residential or nursing care or were a hospital inpatient at the time of the index fall. Participants who refuse consent will be excluded.

Setting/context:

We have chosen 3 research sites which reflect a range of NHS practice to allow for generalisability whilst also providing value for money of the research project. Newcastle upon Tyne is an urban area with primary care provided by two CCGs working together as an alliance, and with emergency secondary care provided by a University teaching hospital with a long track record of innovation in the management of falls. All residents of this CCG live close to the hospital providing emergency care. Hartlepool and Stockton-on Tees cover both urban and rural areas, with a single CCG and emergency secondary care provided by a district general hospital at Stockton-on–Tees, which covers a wide geographical area. Both of these sites are served by the North East Ambulance service. Both currently have dementia diagnosis rates above the national average. Norwich also covers an urban and rural area in the East of England, with primary care provided by a single CCG and emergency secondary care provided by a University Hospital, but dementia diagnosis rates are below the national average.

We have identified 3 potential clinical settings where a future definitive trial of an intervention may seek to recruit patients:

The first setting will be in **primary care**: patients with a known diagnosis of dementia presenting with a fall related injury to any primary care professional at participating practices in the 4 CCGs involved in the study (NHS Newcastle West CCG, NHS Newcastle North and East CCG, Hartlepool and Stockton-on Tees CCG and NHS Norwich CCG).

The second will be in the community: **paramedics** attending calls to a person with possible dementia presenting with a fall related injury. This will apply to calls within the postcodes served by the CCGs described above.

The third setting will be in secondary care: patients with possible dementia, resident within the postcodes served by participating CCGs, presenting to the **emergency departments** of the Royal Victoria Infirmary, Newcastle upon Tyne (RVI), the University Hospital of North Tees, Stockton on Tees (UHNT) and Norfolk and Norwich University Hospital, Norwich (NNUH).

The observational study in WP 2 will take place in all 3 settings at each research site (Newcastle upon Tyne, Hartlepool/Stockton-on Tees and Norwich).

Sampling:

Work Package 2.1 Service Evaluation

We will conduct qualitative interviews with the professionals involved in caring for PWD, and commissioners, to identify their perceptions of the health and social care needs of PWD with injurious falls, important outcomes, ideas for service improvement, barriers and facilitators to change, using a snowball sampling approach.

Work Package 2.2 Service Review

In view of the current waiting lists for some falls-related interventions (and the duration of other interventions), patients participating in the sub study will not necessarily have completed all interventions within the timeframe allocated for WP2. We will therefore recruit up to 12 patients from services which would not otherwise be included in the study (e.g. Staying Steady or strength and balance classes).An understanding of these interventions and their appropriateness for PWD will be gained through observation of existing services and interviews with service providers.

Work Package 2.3 Prospective Observational study

Estimated numbers of community dwelling people with dementia in each site in 2012-13 were: NHS Newcastle West CCG: 1020; NHS Newcastle North and East CCG: 1086; Hartlepool and Stockton-on Tees CCG: 2117 and NHS Norwich CCG: 1993[28]. Current diagnosis rates for each of these CCGs in 2012-13 were 55%, 54%, 54% and 41% respectively, with target diagnosis rates by the end of 2014 being at least 60% in the 3 CCGs in the North East and 54% in Norwich. Prior to commencement of the study we will facilitate a coding exercise in participating practices to ensure that QOF registers are as accurate as possible. If these targets are reached we would therefore be sampling from 3 cohorts of QOF registered PWD numbering 1263, 1270 and 1076 in Newcastle, Stockton and Norwich respectively.

From our previous prospective study of falls in dementia we know that 26% of people with AD, 36% of people with Vascular dementia (VAD) or dementia with Lewy bodies (DLB) and 65% of people with PDD sustain at least one fall related injury per annum [1]. Even taking the most conservative of these groups, if the entire cohort sustains a fall related injury at least as often as those with AD then we would estimate there to be at least 5-6 fall related injuries per week in QOF registered PWD in each of the three sites.

In the observational study in WP 2.3 we firstly aim to quantify in each site the numbers of cases presenting to each of the three settings in whom both a fall related injury and a QOF registered diagnosis of dementia can be confirmed within 72 hours of the initial presentation. This will allow us to estimate the potential numbers of eligible cases to be approached in any future definitive trial. This is essential information informing the feasibility of such a trial. We estimate that a period of 6 months will be sufficient to give a reasonable estimate of monthly presentation rates.

During the first 3 months of the observational period of WP 2 we will aim to recruit PWD at each site to the detailed sub study. These PWD (assisted by family members) will keep diaries mapping their health and social care use. PWD for the sub study will be sampled purposively from each of the three settings to ensure we capture the range of usual care pathways for the target population. It is anticipated that up to an average of 20 patients per site would need to be studied in order to reach saturation of pathways identified (1-2 participants per week at each site). Once data saturation is reached, we will continue to quantify cases, but participants will not be asked to join the sub study.

A purposive sample of up to 21 of these PWD (across all sites) and their key informal carer will be selected for inclusion in the qualitative study. We will ensure that the sample includes PWD from different sites, services and pathways. A purposive sample of up to 36 professionals will also be recruited, ensuring that a range of health and social care providers are included alongside commissioners in each site.

Screening and Recruitment

In primary care, patients on the dementia QOF register will have a flag applied to their records. If a primary care consultation occurs with these patients, the professional will be alerted to determine whether the consultation is due to a fall related injury and if yes, the consultation will be added to the screening log. Consent will then be sought from the patient and/or their carer for the research team to contact the person with further information about the study. When a consultation with consent for contact is recorded on the log an alert will be forwarded to a clinical trials assistant (CTA) in the relevant clinical research facility (Newcastle or Norwich), prompting them to contact the practice for details. The CTA will keep in regular contact with the participating practices to ensure that practices remain aware of the log and to identify and resolve any obstacles which become apparent.

In the community, paramedics attending a person with a fall routinely refer the person to the local integrated falls services via a dedicated telephone number. Basic information about co-morbidities is sought by the person receiving the referral at the time of the referral. During the period of recruitment the teams will be asked to include a question about whether it is *possible* that the person may have dementia. This information may be obtained by a direct history of known dementia or confusion from the person or their carer, or if not available if the person appears to be confused in the opinion of the paramedic. All persons with possible dementia who have sustained an injury will be added to the screening log. The paramedic will be prompted to seek verbal consent for the research team to contact the person with further information about the study. The CTA at each site will contact the ambulance service 5 days per week to receive details of potential participants.

In secondary care staff in the ED also routinely refer to an integrated falls service when a person presents with a fall related injury. Staff seeing such patients will be prompted to record those with *possible* dementia in the screening log at the time of the consultation. All persons added to the screening log will be asked to consent to contact by the research team with further information about the study. The CTA at each site will monitor the log 5 days per week for potential participants. They will make a record of any duplicates presenting to ED via the paramedics and recorded on both logs.

Data collection:

Work Package 2.1 Service Evaluation

We will conduct qualitative interviews with the professionals involved in caring for PWD, and commissioners, to identify their perceptions of the health and social care needs of PWD with injurious falls, important outcomes, ideas for service improvement, barriers and facilitators to change. To ensure data collection is completed within the time frame, most professionals will be interviewed at the start of WP2. Additional interviews will be scheduled during WP2.3 with any professional groups newly identified via the diaries.

Work Package 2.2 Service Review

We will undertake observation of selected service elements identified in the diaries (and services to which patients have been referred but are still awaiting appointments). This will enable us to develop a more detailed understanding of the pathways. We will observe up to six services in each site and anticipate that this will include exercise classes (e.g. 'Staying Steady') and falls clinics. Services with waiting lists known to extend beyond the timeframe of WP2 will be observed at the outset of WP2 to ensure that data collection is completed on time.

Work Package 2.3 Prospective Observational study

A CTA in each site will maintain the screening log from the three settings. We will also monitor the referral systems of the integrated falls services in each of these areas to log cases not identified at their source of presentation. The CTA will require access to clinical notes (copies of GP records, paramedic records, ED records and acute hospital notes as appropriate) for this step. We will apply for approval by the Confidentiality Advisory Group to enable access to this confidential information. The lists of potential patients will include NHS/hospital number, date of birth and name to facilitate retrieval of notes. This information will be recorded in a separate administrative database and kept in a password protected file on a NHS Trust computer. Each patient will be allocated a unique study identifier. All data extracted from the casenotes and recorded for the study will be identified only by the unique study identifier. While access to patient identifiable information is inevitable to confirm the presence of dementia, the CTA will record only minimal information from this initial screening, using the unique study identifier to record age, sex, injury and diagnosis. The diagnosis of known dementia will be confirmed by triangulating evidence from medical notes, the medication history, mental health trust registers and GP QOF registers. Where the patient is not on the QOF register but other information suggests they should be the GP will be asked to review the patient's Read codes and advise whether they believe the register should be revised to include the patient. For those PWD who have not given consent to contact by the research team the only data to be retained will be age, gender, confirmed diagnosis of dementia and type of injury.

Where a PWD has given permission (or their carer in cases where the patient lacks capacity to do so) for direct contact by the research team, the most appropriate route of contact for that patient will have been sought by the health professional seeking consent. A clinical research nurse will use these details to contact the PWD and/or carer as soon as possible and within at most 72 hours of their index fall. The nurse will arrange to visit the PWD and carer at home or in hospital if they have been admitted, to further explain the study and seek consent for participation in the sub study. PWD and their carers who agree to continue to the sub study will be asked undertake a prospective diary exercise for 12 weeks. For those who are admitted to hospital we will estimate their service usage during the admission from a review of hospital records; following discharge we will ask such participants to keep diaries of their ongoing service usage.

The nurse will obtain the patient's medical history, medication history, dementia subtype and further details of the type and code of injury, location and circumstances of the fall, early treatment, any referral made by the attending professional and involvement of a carer, using a structured proforma. The use of the diaries will be explained and patients will be asked whether they would additionally be willing to take part in a qualitative interview.

Diaries

The design of the diaries will be based upon those used in our previous study of falls in PWD; these were successfully completed by the majority of participants with return rates over 80%. Each diary will cover a period of 4 weeks and entries are made daily if an event occurs; at the end of each diary the next will be sent with a pre-paid return envelope. In the event of non-return the project administrator will contact the participant by telephone. Event data collected in the diary will be a record of each contact with a health or social care professional, whether in the home or at GP surgery, hospital or clinic and records of any further falls or injuries. This will enable us to track the care pathways followed by the participants. Services identified will be contacted and data collected regarding staffing levels and training in dementia care. Where PWD have been seen by a falls service the medical notes will be examined to identify specific components of falls prevention which have been received.

Health Economic data

The information from the diaries tracking service usage will be used to pilot the collection of health economic data. This information will be used to help design the service utilisation data collection tool for the economic analysis. The diaries will be constructed in a way to collect all relevant information on service use while not overburdening PWD and their carers. By collecting data prospectively on a daily basis the possibility of recall bias will be reduced (potentially an issue when dealing with PWD).

Qualitative study

We will conduct semi-structured interviews with approximately 21 patient-carer dyads (divided between each setting). Where possible we will interview patients and carers separately, however, we recognise that some patients will prefer a joint interview. Interviews will take no longer than 60 minutes and will be audio recorded, transcribed verbatim and analysed thematically using the constant comparative approach. Interviews will include questions to explore PWD and carer perceptions of their care needs, whether they were met, what might have been improved and what outcomes were important to them. Outcomes to be considered for inclusion in discussions will cover the domains included by the most relevant publications we have found on the COMET initiative database: the ProFaNE Consensus on a common outcome data set for fall injury prevention trials[26] (domains include falls, injuries, psychological consequences of falling, HRQoL, physical activity) and those identified by the European Consensus on outcome measures for psychosocial intervention research in dementia care[27] (domains include patient mood, quality of life, activities of daily living and behaviour, and carer mood and carer burden). Other domains may be identified by our PPI panel and the participants themselves. The timing of the interviews will vary according to the complexity of the pathway. For patients with minor injurious falls where no or minimal follow-up is anticipated, we will aim to interview patients as soon as possible after the index fall to maximise recall. Where patients receive a number of interventions some will be interviewed towards the end of the pathway to try to obtain a holistic view of the care received, others will be interviewed as soon as possible after specific interventions to explore these in more detail.

Consent procedures

The participants will also be required to give informed consent to participation in accordance with the declaration of Helsinki. Due to the nature of dementia, some participants may lack the capacity to give full informed consent. In this case we will follow the provisions of the

Mental Capacity Act (2005). Participants will be asked to give consent appropriate to their level of understanding, ranging from written informed consent to account being taken of verbal and non−verbal communication in determining willingness to participate. In those individuals found to be without capacity to give full informed consent, the research nurse will identify a personal or nominated consultee and seek their advice regarding participation. Any patient appearing distressed by participation or withdrawing consent will be excluded from the study without prejudice to clinical care.

Data analysis:

Participant characteristics will be analysed using descriptive statistics. Monthly presentation rates of potentially eligible participants will be calculated for each setting and compared between sites, giving an estimate of the potential future demand for an effective complex intervention within the NHS. The proportion of potentially eligible participants consenting to initial contact and then to full participation in the sub study will be calculated, giving an indication of likely recruitment rates to WP4 and any future clinical trial.

Diaries

The diaries will be analysed quantitatively and thematically. The proportion of PWD admitted to hospital, procedures performed and length of stay will be quantified and differences in patient characteristics will be compared with those not admitted. The proportion of PWD receiving individual components of a multifactorial falls prevention intervention will be calculated. Thematic analysis will identify the most common trajectories through the available services and these will be compared with participant characteristics, by setting of recruitment and between research sites. Staffing levels and education in dementia care will be compared by site and category of service.

Health Economic data

Data on the diaries will be used to identify the types of services used. The data will not be summarised as descriptive statistics rather the data will be summarised as a set of headings e.g. GP consultations, occupational therapy visits, etc. These data will be used to construct a data collection tool for use in WP4. The data collection tool will be constructed in a way to collect all relevant information on use of services (i.e resource use) while not overburdening participants.

Qualitative study

The interview transcripts and field notes from observation will form the formal data for analysis. 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 and observation. Data collection and analysis will be informed by Normalization Process Theory (NPT); this provides a framework for assessing the likelihood of a new intervention or practice becoming embedded into routine clinical practice[29]. This theory is increasingly being used in studies of the implementation of interventions in health care (www.normalizationprocess.org) including active (STRIDE study, HTA ref 09/70/04; CB, SWP) and published studies from the current applicants.

The data analysis will be summarised in reports for the expert members of the Consensus and also in a format accessible to PPI members of the panel. Reports will summarise: the numbers of PWD presenting to health services with a fall related injury in 3 different UK sites and proportions presenting to each type of service and admitted to hospital, the current observed UK care pathways of PWD sustaining fall related injuries, the patients' and carers' perceptions of their experiences and best practice examples and the views of key professional views on how to improve practice and overcome barriers to implementation of new interventions. These reports will be sent to the panel for review in advance of the first meeting.

Work package 3:

Health technologies being designed:

In WP3 we will convene a consensus panel to review the findings of the prior work packages. The panel will be made up of 10 expert health and social care professionals and members of our PPI panel. They will use the information from WPs 1 and 2 to make recommendations regarding the design of the complex intervention. They will assess, discuss and make recommendations regarding the feasibility of recruiting participants to a future definitive trial. If feasible, they will make recommendations as to the setting for recruitment, the content of the intervention and the outcome measures to be recorded. A fully manualised description of the intervention and accompanying training materials will then be produced by the research team.

Design and theoretical/conceptual framework:

The recommendations of the panel regarding the design of the intervention will be assimilated using methods of the RAND Nominal Group Technique (NGT-R, also known as the modified Delphi panel approach). NGT-R uses structured interaction within a group and is commonly applied when decisions and care needs are complex and the evidence base is limited. This approach will ensure the design of the new intervention takes account of the full range of stakeholders' views and not just the views of the research team. The panel will meet twice: initially to discuss the evidence presented from WPs 1 and 2 and secondly to review the manualised procedures for the trial. Between the two meetings online surveys will be used to undertake the structured interactions required to achieve consensus on the design and setting of the intervention in WP 4 and the content of the manualised procedures for delivery and outcome measurement. The research team will develop manuals for the intervention as themes emerge from the Delphi panel. A further qualitative study will present the

manuals back to with a range of stakeholders including those identified in WP2 to explore the acceptability of the proposed intervention before it is finalised for WP4.

Data collection and analysis:

Delphi Panel

The panel will meet to discuss the findings of the reports, firstly from WP1 then WP2. Members will split into groups and notes of the discussions at each table will be taken by a facilitator from the research team. Groups will then report back to each other and areas of initial agreement and dissent will be identified. Following the first meeting the research team will summarise the discussions of the panel and circulate prior to the first Delphi round. Member will then be invited to complete up to 3 rounds of structured surveys via the project website. Members will be asked to respond to specific questions about whether the recruitment to WP4 and any subsequent trial is feasible, in which setting a trial should aim to recruit participants, components of the complex intervention and suitable outcome measures, including HRQoL for health economic analysis. There will be opportunity to give brief reasons for their decisions. After each round the research team will summarise comments and present these together with the proportion agreeing with each question back to the panel. Members will then have the opportunity to revise their responses at each round until a majority consensus for each specific questions is reached and a draft trial manual will be produced for the second meeting.

Qualitative study

We will invite up to six patient/carer dyads who participated in WP2 to take part in a further interview to review and discuss the proposed intervention. The consent form for WP2 will ask permission to contact the patient/carer again regarding WP3; a separate consent form will be completed at the time of WP3 for this part of the study. We will seek feedback on the proposed intervention via a focus group with a range of professionals who participated in WP2 at each site. Up to six individual interviews will also be conducted with key professionals from WP2 who are unable to attend a focus group. Interviews and focus groups will be transcribed verbatim for analysis. The interviews and focus groups will explore the acceptability of the proposed intervention to stakeholders and the 'fit' of the intervention within the organisation and delivery of existing services. They may also highlight new potential barriers and facilitators which will inform the final version of the intervention.

A written summary of key comments from the consultations with stakeholders will be provided for the second meeting of the consensus panel. The focus groups and interviews will be transcribed and anonymised for subsequent integrative analysis with WP4 data. Analysis of the qualitative data will follow the same procedures as outlined for WP2.

At the second meeting of the panel the manuals and summary of consultations will be considered by the panel. Discussions will be facilitated and notes taken as at the first meeting. The comments of the panel will be considered by the research team and the trial manual will be adjusted as necessary. The materials and patient information sheets will be then submitted for ethical review. At this point we will be able to finalise the costs of the intervention in WP4 and we will submit these to the NIHR for final approval.

Work package 4:

Health technologies being assessed:

Once a new intervention is designed it needs to be assessed in a phased approach, via pilot studies which explore the feasibility of implementation and address any uncertainties in design. In WP4 we will undertake a rehearsal of the intervention in a pilot study. We will assess the feasibility of participant recruitment to a clinical trial of the health intervention, assess the fidelity of delivery of the intervention, assess variability of delivery between sites and assess the feasibility of outcome measurement. In a qualitative study we will assess the factors influencing the acceptability and implementation of the intervention. The evidence from WP 4 will be used to make recommendations regarding any necessary changes in the design of the intervention which would be required before planning a definitive evaluation of the intervention.

Design and theoretical/conceptual framework:

WP4 will test the procedures for implementation of the intervention and measurement of outcomes recommended in WP3, in the form of a pre-trial evaluation. We will test the feasibility of delivery of the intervention within present NHS structures, and test acceptability, adherence to delivery of the intervention and outcome measurement.

A qualitative study will be performed using NPT to assess factors influencing the acceptability and implementation of the intervention.

Target population: as WP 2

Inclusion/Exclusion Criteria: as WP 2

Setting/context:

In WP 4 we will again undertake our research at each of the three sites, but the final decision regarding the settings to be included at each site will be determined by the consensus panel in WP 3. This may include one, two or all of the settings studied in WP 2.

Sampling:

In WP 4 we will aim to recruit a total of 15 participants in each site over a period of 2 months (2 participants per week per site). We anticipate that the panel would consider this recruitment rate to be the minimum required to justify a subsequent definitive trial. Recruitment and consent procedures will be as for WP2.

Data collection:

Following recruitment and consent a clinical research nurse will obtain the patient's medical history, medication history, dementia subtype and further details of the type and code of injury, location and circumstances of the fall, early treatment, any referral made by the attending professional and involvement of a carer, using a structured proforma as in WP2. Diaries will be used as in WP2, including any adjustments made to the design as a result of our analysis and the views of the consensus panel. The use of the diaries will be explained by the nurse and patients will be asked whether they would additionally be willing to take part in a qualitative interview regarding their experiences of the intervention. The intervention will be delivered according to the manuals developed in WP3. The manuals will be developed to facilitate collection of clinical data relevant to each component included in the intervention. Depending on the intensity of the intervention we may need to collect data regarding delivery of the intervention in different ways. In the case of a low intensity intervention, data regarding health care treatment may be taken solely from the diaries and review of medical notes. In this case measurement of fidelity of the intervention would be based upon records of delivery of any face to face education, completion of interactive materials and assessment of staff knowledge and attitudes towards PWD. In the case of a medium intensity observation, research staff delivering a consultative service will keep structured records of recommendations made and medical notes will be reviewed to assess compliance with recommendations. In the case of a high intensity intervention we would anticipate that clinical staff would be trained in the delivery of multiple components using a structured manual with associated proformas to record delivery of each component. In this case we will assess delivery of each component against the structured advice; e.g. if a medication review is required to identify medications which might exacerbate confusion, we will check whether all known culprit medications were identified and either stopped or a reason for the variance recorded.

Primary and secondary outcomes

The procedures for collection of data for primary and secondary outcomes will depend upon the outcomes chosen and may include patient and/or carer related outcomes using structured questionnaires, or researcher or clinician rated outcomes based upon clinical assessments and measurements. Most of the dementia specific outcome domains and some fall related outcome domains identified for consideration can be assessed using validated questionnaires; e.g. mood assessed by the Cornell Depression Scale[30], activities of daily living using the Bristol ADL scale[31], behaviour using the Neuropsychiatric Inventory[32], psychological consequences of falls using the modified Falls Efficacy Scale[33]. Such questionnaires would be administered by the CTA. Outcome data related to further falls and injuries will be assessed using the diaries. The data for health economic evaluation will be collected using the service utilisation data collection tool created in WP3. This will be an integral part of the diaries used to collect information about falls.

Qualitative study

We will explore stakeholder views of the intervention through semi-structured interviews. We will interview up to five patient/carer dyads in each site; where possible arranging separate interviews with patients and carers. The timing of the interviews will be informed by the intervention; for example, if the intervention is multifaceted, then we will schedule some interviews to coincide with completion of different aspects of the intervention; this will facilitate recall of specific components by PWD. If feasible within the timeframe, we will also schedule some interviews on completion of the intervention to gain a holistic view. We will interview up to six professionals responsible for delivering the intervention; interviews will take place throughout WP4 to enable comparison of their views at the beginning and end of the pilot feasibility study and explore whether and how implementation of the intervention has changed over time. Interviews will also be conducted with up to nine colleagues and professionals in related services (three in each site). These interviews with a range of stakeholders will explore their experiences of the intervention, the 'fit' of the intervention with other services, suggested changes or improvements to the content, delivery or timing of the intervention and perceived outcomes. We will also observe training and intervention delivery if at all possible (this will depend on the nature and delivery of the intervention). We would aim to observe the delivery of all components of the intervention in all sites assuming this is logistically possible.

Data analysis:

Delivery of the intervention, primary, secondary and health economic outcomes

We will assess and present rates of delivery for each component of the intervention in summary and at each site.

The data collected from the pilot study will be assessed and presented as summary statistics; this will allow our results to be used for meta-analysis and systematic reviews. Our main focus will be on completion rates of the diaries and other outcomes measures. We will look at the overall response rates and the completion of each primary and secondary outcome measure and each question in the service utilisation data collection tool. This will help us identify potential issues (if any) with the data collection tools and amendments can be made accordingly. While the intervention and data collection tools are being piloted the costs associated with the intervention and resource use will be identified. This will determine the ease of cost collection for a full definitive trial.

Qualitative study

All field notes and interview transcripts will be anonymised to facilitate the involvement of members of the extended team in the process of data analysis. Following the principles of the constant comparative method, we will produce a cumulative, integrative analysis which

includes the qualitative data from WP2, WP3 and WP4. This will provide a detailed exploration of the extent to which views on the intervention and facilitators/barriers implementation are consistent within and between stakeholder groups and with the existing care pathways identified in WP2.

Combining data from different data sets and integrating different viewpoints can be challenging. To synthesise data from different sources we will develop a common coding frame for all data, accepting that some codes may be more pertinent to some sources/perspectives than others. Our previous experience of doing this has shown that coding in this way illuminates difference or absence within the data and informs future data collection, with the coding frame being refined over time as more data are collected and analysed. NVivo, a form of data analysis software, will be used to manage data analysis.

Some data analysis clinics will also include members of the extended team (LA, LC, LR) where we will discuss findings and compare the data from different stakeholders and sites. We have used this approach in the past and found that co-investigators often provide new insights into possible interpretations of the data which can be explored in subsequent analysis and through further data collection.

The analysis will be informed by Normalization Process Theory (NPT); this provides a framework for assessing the likelihood of a new intervention or practice becoming embedded into routine clinical practice. NPT considers factors that affect implementation in relation to four key areas; how people make sense of a new practice (coherence); the willingness of people to sign-up and commit to the new practice (cognitive participation); their ability to take on the work required of the practice (collective action); and activity undertaken to monitor and review the practice (reflexive monitoring). This theory is increasingly being used in studies of the implementation of interventions in health care (www.normalizationprocess.org) including active (STRIDE study, HTA ref 09/70/04; CB, SWP) and published studies from the current applicants.

Final Recommendations

The final recommendation will synthesise both the qualitative and quantitative findings from WP4. The report will identify any factors which would be likely to make a future trial unfeasible. If a trial is feasible we will make a recommendation as to the optimum design and setting for the trial and discuss potential facilitators and barriers to its completion. Where barriers are identified, we will describe any recommended changes to the procedures and manuals used in WP4. A final report will be submitted to the HTA Journal.

Dissemination and projected outputs:

Our communication plan is designed to achieve maximum impact for our work among clinicians, patient groups and researchers, and so in addition to academic channels we will partner with the Alzheimer's Society and Dementia UK to develop the public/patient message. This has been critical in our previous projects in the field. We will set up a study website which will summarise the WPs to be undertaken and provide public information regarding their progress and findings.

For patients and members of the public, we will produce a programme newsletter which will be made available to participants, uploaded to the study website and made available in newsletters provided by voluntary organisations (Alzheimer's Society, Age UK). We will present our findings at DeNDRoN PPI groups and local PPI groups.

For researchers and professionals, the systematic reviews in WP 1 will be registered on the PROSPERO database of systematic reviews and progress will be reported on the website. We will also use our multidisciplinary links to publicise the findings on relevant professional websites (e.g. the British Geriatrics Society). Further links will be established as part of the WP1, where we will surveying current practice. We will disseminate the results of our study to identified links and signpost them to our website. The findings of each WP will be presented at scientific meetings and published in peer-reviewed journals. We will target open access publications to maximise availability. We will aim to present at 2 Conferences for example at the BGS and American Geriatric Association meetings.

For policy makers and commissioners, we will publish articles in appropriate periodicals and journals and provide signposting to our website. We will use our links in the Dementia Action Alliance and other voluntary organisations to identify key policy groups.

Social media- we will use Twitter to provide relevant details of any new publication, website update or new blog that the project completes. To gauge feedback, we will send a tweet that links to a research blog and ask our followers for their feedback and comments. Our university media departments Twitter will be part of our communication package.

Finally, the findings of the research will be reported in the NIHR HTA Journal, describing whether it has been possible to design an intervention which may improve outcomes for community dwelling PWD with fall related injuries. If it has been possible to design such an intervention, we will describe how recipients should be identified, describe and manualise the key components of the intervention, recommend how and where it should be delivered, and by whom. We will describe the learning needs of the professionals delivering the intervention and produce appropriate educational materials.

Patient and Public Involvement

This research question addressed in this call was identified by the HTA with patient and public involvement. We have shared the brief and plans for this project with older people and carers of PWD participating in Voice North - an organisation to facilitate the involvement of the public in research and product and service development. Voice North exists to harness the skills and experience of the public- currently over 1000 people are involved from across the North East. The participants concurred with the HTA's view that this is an important area

for research into the care of PWD. Two participants were informal carers of PWD and one had experience of caring for their father following fall and fractured femur. The participants identified that the views of people who have been recent carers of PWD are often overlooked in this area of health care and identified them as potential sources of learning.

They also identified a potential role for PWD and carers in being part of the research team; this could be achieved by inviting PWD and carers to take part in the preparation of the evidence to be presented to the consensus panel.

The progress of this study will be overseen by a project management group and we will ensure that this group includes PWD and informal carers of PWD. Prior to undertaking the qualitative study in WP2, we will hold a focus group drawing on contacts from Voice North and DeNDRoN PPI groups to inform the range of topics to be explored in qualitative interviews. PWD and carers will also be involved in the preparation of information sheets and consent forms to be given to participants in the study and the preparation of applications for ethical approval. With appropriate training, we will invite PWD and carers to be involved in the preparation of reports on the findings of WP 2 and 3 before they are submitted to members of the consensus panel, and they will also be included in the consensus panel itself. They will be invited to contribute to any educational interventions developed as part of the pilot intervention. PWD and carers will be invited to participate in the preparation and execution of the dissemination plan, and presentation to PPI groups will be a major focus of the dissemination plan.

Project management

The study will be sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust. A formal agreement between the Sponsor and each participating site, setting out the responsibilities of Sponsor, Chief Investigator and Site, including site PI, will be in place prior to site initiation. Evidence of local approvals including NHS organisation R&D and Caldicott Guardian will be obtained prior to site initiation.

The study overall will be managed by a Project Management Group (PMG) comprising the co-investigators and chaired by the principal investigator (LMA). The database and project manager will have day to day oversight of the project with the principal investigator, while the qualitative studies will be managed by CB. Milestone progress will be reviewed on a week to week basis by LMA and CB, together with project staff, with action taken in tandem with the steering group if any deviation from milestones is anticipated. The PMG will meet in full at least once during each work package using teleconference and face-to-face meetings and every month for central staff in Newcastle throughout the course of the project.

A Trial steering committee with 75% independent membership will provide overall supervision for a trial on behalf of the Trial Sponsor and Trial Funder and to ensure that the trial is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

Approval by ethics committees

The project requires access to clinical notes by staff outside the usual healthcare team; this requires either informed consent or approval by the Confidentiality Advisory Group (CAG). We will apply for CAG approval for the screening element of WP2 and 4. The lists of potential patients will include NHS/hospital number, date of birth and name to facilitate retrieval of notes. This information will be recorded in a separate administrative database and kept in a password protected file on a NHS Trust computer. Each patient will be allocated a unique study identifier. All data extracted from the casenotes and recorded for the study will be identified only by the unique study identifier. While access to patient identifiable information is inevitable to confirm the presence of dementia, we will record only minimal information from this initial screening, using the unique study identifier to record age, sex and diagnosis. All staff responsible for note screening and review will have undergone appropriate training and will work to established codes of conduct.

For participants in the sub study we will obtain informed consent. Due to the nature of dementia, some participants may lack the capacity to give full informed consent. To protect these participants we will comply with the terms of the Mental Capacity Act (2005). In this case participants will be asked to give consent appropriate to their level of understanding, ranging from written informed consent to account being taken of verbal and non−verbal communication in determining willingness to participate. In those individuals found to be without capacity to give full informed consent, the research nurse will identify a personal or nominated consultee and seek their advice regarding participation. Any patient appearing distressed by participation or withdrawing consent will be excluded from the study without prejudice to clinical care.

Funding Acknowledgement:

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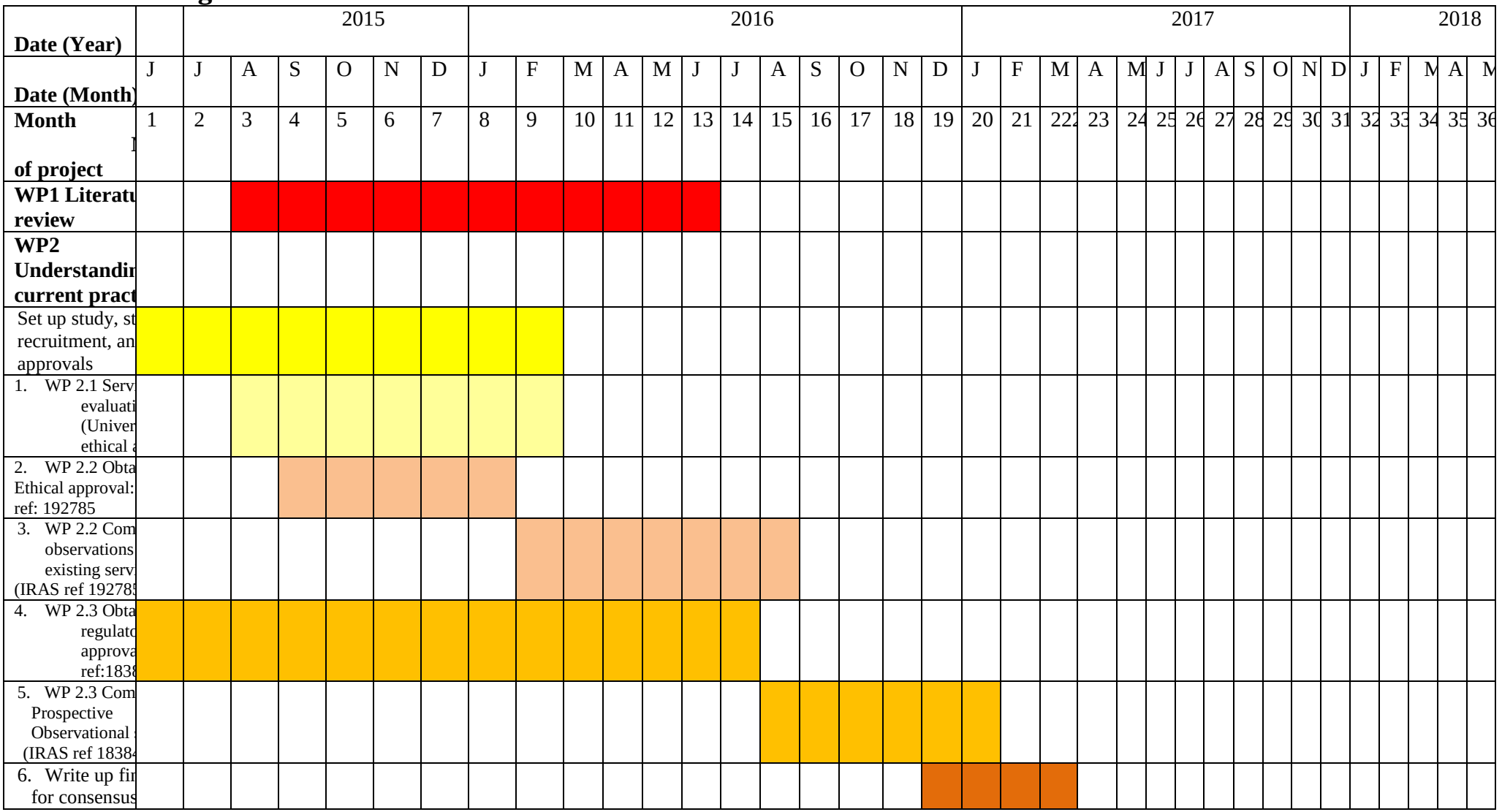
Plan of investigation and timetable:



Date (Year)		2015						2016												2017												2018				
Date (Month)	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M
Month of project	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
WP3 Interven development validation																																				
1. Appoint par																																				
2. Consensus meets																																				
3. Proposed intervention presented to stakeholders																																				
4. Finalise intervention f obtain approv																																				
WP4 Pilot implementati																																				
1. Participant enrolment an baseline asse																																				
2. Follow assessments																																				
3. Proces evaluation																																				
Write up and dissemination																																				

Expected Outputs

Work package 1: Literature review by month 13

- Summaries of current evidence and guidelines supporting best practice
- Identification of potential components of a complex intervention to improve outcomes of fall related injury in PWD
- Conference presentation
- Peer reviewed publication

Work package 2: Understanding current practice by month 22

- Report of the numbers of PWD presenting to health services with a fall related injury in 3 different UK sites and proportions presenting to each type of service and admitted to hospital
- Summaries of current observed UK care pathways of PWD sustaining fall related injuries
- Report of patients' and carers' perceptions of their experiences and best practice
- Report of key professional views on how to improve practice and overcome barriers to implementation of new interventions
- Conference presentation
- Peer reviewed publication

Work package 3: Intervention development and validation by month 27

- Consensus report on the optimal components of a pilot complex intervention to improve outcomes of fall related injury in PWD, description of primary, secondary and health economic outcomes to be measured and recommendation regarding the trial setting
- Education manuals for delivery of the recommended pilot intervention
- Report of patients', carers' and professionals' perceptions of the proposed pilot intervention
- Peer reviewed publication

Work package 4: Pilot implementation of the intervention by month 36

- Identification of difficulties with the delivery of the intervention and collection of outcome data
- Summary statistics of completeness of outcome data
- Evaluation of whether staff behaviour has changed
- Narrative account of the pilot intervention with qualitative data on experiences and perceptions of patients, carers and professionals
- Conference presentation
- Peer reviewed publication
- Report to HTA Journal

Appendix 1

The appropriate Read codes for adding a person to a GP dementia QOF register have been described by Russell et al [34]and are available at: http://bmjopen.bmj.com/content/suppl/2013/12/20/bmjopen-2013-004023.DC1.html

Where some diagnostic data are available the codes **Eu00.** can be used for Alzheimer's disease, **Eu002** for mixed dementia, and **Eu01.** for vascular dementia. All others can be given **Eu02z.**

Recommended READ codes

ICD	Diagnosis	READ
F00	Dementia in Alzheimer's disease	**Eu00.**
F00.2	Dementia in Alzheimer's disease, atypical or mixed type ("Mixed Dementia")	**Eu002**
F01	Vascular dementia	**Eu01.**
F03	Unspecified dementia	**Eu02z**

Where detailed information on subtype of dementia is available, then the READ codes below can be used. This matches ICD10 codes to recognised general practice dementia READ codes.

All READ codes

ICD10	Diagnosis	READ
F00	Dementia in Alzheimer's disease	Eu00.
F00.0	Dementia in Alzheimer's disease with early onset	Eu000
F00.1	Dementia in Alzheimer's disease with late onset	Eu001
F00.2	Dementia in Alzheimer's disease, atypical or mixed type	Eu002
F00.9	Dementia in Alzheimer's disease, unspecified	Eu00z
F01	Vascular dementia Arteriosceloritic dementia	Eu01. E004
F01.1	Multi-infarct dementia	Eu011
F01.2	Subcortical vascular dementia	Eu012
F01.3	Mixed cortical and subcortical vascular dementia	Eu013
F01.8	Other vascular dementia	Eu01y
F01.9	Vascular dementia, unspecified Uncomplicated arteriosclerotic dementia Arteriosclerotic dementia with delirium Arteriosclerotic dementia with paranoia Arteriosclerotic dementia with depression Arteriosclerotic dementia NOS	Eu01z E0040 E0041 E0042 E0043 E004z
F02	Dementia in other diseases classified elsewhere	Eu02.
F02.0	Dementia in Pick's disease	Eu020
F02.1	Dementia in Creutzfeldt-Jakob disease	Eu021
F02.2	Dementia in Huntingdon's disease	Eu022

F02.3	Dementia in Parkinson's disease	Eu023
F02.4	Dementia in HIV disease	Eu024
F02.8	Dementia in other disease classified elsewhere Dementia in conditions	Eu02y E041
F03	Unspecified dementia	Eu02z
	Presenile dementia	E001.
	Uncomplicated presenile dementia	E0010
	Presenile dementia with delirium	E0011
	Presenile dementia with paranoia	E0012
	Presenile dementia with depression	E0013
	Presenile dementia NOS	E001z
	Uncomplicated senile dementia	E000
	Senile dementia with depressive or paranoid features	E002
	Senile dementia with paranoia	E0020
	Senile dementia with depression	E0021
	Senile dementia with depressive or paranoid features NOS	E002z
F05.1	Delirium superimposed on dementia	Eu041
	Senile dementia with delirium	E003
F05.9	Delirium, unspecified	Eu04z
F06.0	Organic hallucinosis	Eu050
	Other senile and presenile organic psychoses	E00y
	Senile or presenile psychoses	E00z
F06.7	Mild cognitive disorder	Eu057
F10.7	Residual and late onset psychotic disorder due to alcohol.	Eu107
	Including:	Eu10711
	- Alcoholic dementia	E012
	- Other alcoholic dementia	E0120
	- Chronic alcoholic brain syndrome	
G30	Alzheimer's disease	F110.
G30.8	Other Alzheimer's disease	
G30.9	Alzheimer's disease, unspecified	
G30.0	Alzheimer's disease with early onset	F1100
G30.1	Alzheimer's disease with late onset	F1101
G31.0	Circumscribed brain atrophy. Including;	
	- Fronto-temporal dementia	No Code
	- Pick's disease	F111.
	- Progressive isolated aphasia	
G31.1	Senile degeneration of the brain, not elsewhere classified	F112.
G31.8	Other specified degenerative disease of the nervous system. Including:	
	- Grey matter degeneration	
	- Lewy body disease	F116
	- Lewy body dementia	Eu025
	- Subacute necrotizing encephalopathy	