PROTOCOL V2 (Current from: 13.12.2012)
Detailed Project Description submitted to NIHR

Full title of project: The prevalence of visual impairment in people with dementia

Aims and objectives

The risks of developing both dementia and visual impairment (VI) increase with age, so a large population of people in the UK affected by dementia may also have VI. Demographic research predicts an ageing UK population resulting in increasing prevalences of dementia and the major causes of VI. A brief review of literature on VI and dementia revealed inconclusive prevalence data due to methodological differences in subjects' age, research setting (care home residents and non residents) and definitions of VI. Furthermore, much of the research is 10-30 years old and few studies were UK based. This led to identification of the main research question which is: What is the prevalence of a range of vision problems in people with dementia aged 60-89 years and to what extent are these conditions undetected or inappropriately managed?

The objectives are:

1. To measure the prevalence of a range of vision problems in people with dementia.
2. To compare the prevalences found in Objective 1 with the published data on the general population in a comparable age range.
3. To identify and describe reasons for any under detection or inappropriate management of visual impairment in people with dementia.
4. To recommend interventions to improve eye care for people with dementia and further research in this area.

Background

The risks of dementia and visual impairment (VI) both increase with age so it is probable that a large proportion of people with dementia may also have VI. UK demographic changes suggest that ever-increasing numbers of people will be affected by both conditions. However, good quality prevalence data on the topic are lacking.

A PubMed search for prevalence of visual impairment & eye disease in the elderly was conducted using the following search strategy: (elderly[tiab] OR "aged"[MeSH Terms] OR geriatric[tiab] OR older) AND ("eye diseases" OR "eye disease" OR "eye diseases" OR "visual acuity" OR "vision disorder" OR "vision disorders" OR "visual impairment" OR "refractive error" OR "refractive errors" OR glaucoma OR presbyopia OR myopia OR astigmatic OR astigmatism OR cataract OR cataracts OR "retinal diseases"[MeSH Terms] OR "retinal diseases"[All Fields] OR retinopathy OR retinopathies OR "diabetic eye disease" OR "macular degeneration" OR "low vision") AND (("epidemiology"[Subheading] OR "prevalence"[All Fields] OR "prevalence"[MeSH Terms]) OR epidemiology[tiab])

The search identified 9035 papers. These studies vary as to whether the study deals with a single eye disease, or several; whether it only addresses eye disease prevalence or includes it in a study of several pathologies. Only a small number of papers found via this search, and from reference list searches of review articles and reports, specifically address the prevalence of visual impairment in a large sample of elderly people in the UK, although a wider body of international prevalence data exists.

A number of conditions cause visual impairment (VI) or blindness in elderly people and yet many cases can be either prevented or successfully treated with early detection and correct management. The reported prevalence of VI in the general population of people aged 65 and older varies from 14.3% (3), to 30% (4) and even 50.5% (5), with the differences mainly due to study methodology. Refractive error (reduced vision correctable with spectacles) in the same age group has been similarly reported as ranging between 9% (4) and 40% (5). Age

related macular degeneration (AMD) is estimated to cause vision loss in 3.5% of people aged 70-85 years (6). Glaucoma affects 3.3% of over 70 year olds (7). Diabetic retinopathy has been found in nearly 30% of diabetics aged 65 years and over (8).

Age related cataract is the most common cause of reversible blindness (9) causing VI in 16% of 65-69 year olds rising to 71% in people 85 years and over (5). Evans et al (10) concluded that there is overwhelming evidence that a very large proportion of older people do not receive appropriate eye care and many of these people could be helped by cataract surgery or appropriate refractive correction (spectacles).

A search of PubMed was conducted for papers dealing with the prevalence of eye disease and/or visual impairment in those with dementia using the following terms: (dementia OR alzheimer's[tiab]) AND ("eye diseases" OR "eye disease" OR "eye diseases"[MeSH Terms] OR "visual acuity" OR "vision disorder" OR "vision disorders" OR "visual impairment" OR "refractive error" OR "refractive errors" OR glaucoma OR presbyopia OR myopia OR astigmatic OR astigmatism OR cataract OR cataracts OR retinopathy OR “retinal disease” OR "diabetic eye disease" OR "macular degeneration" OR "low vision") AND ("epidemiology"[Subheading] OR epidemiology[tiab] OR prevalence[tiab] OR prevalence[MeSH Terms]). The search retrieved 232 papers. A hand search found that 10 were prevalence studies, and of those 10, none were UK papers.

The literature review on VI and dementia revealed inconclusive data on prevalence due to methodological differences in the age of subjects studied, research setting (care home residents and non residents) and definitions of VI. Furthermore, much of the research is 10-30 years old and again has limited UK focus. Supporting this, a report commissioned by Thomas Pocklington Trust (TPT) highlighted shortcomings in guidance on care for people with dementia across the eye care professions (1).

Studies investigating VI and dementia have revealed shared changes in nervous system physiology and suggest that the prevalence of VI in people with dementia is higher than in the general population (11). Patients with dementia not only suffer the general visual problems associated with ageing but also experience visual disturbances as a result of the damage to, or degeneration of, the brain (12) which can make the differential diagnosis of "eye problems" from functional vision loss caused by dementia or stroke more difficult.

“Free” eye tests, funded by the NHS, are available to everyone over the age of 60; 53% of over 60s have an annual sight test, 35% every two years and 11% less often (13). Uptake among people with dementia is thought to be considerably less (1, 14). One study found that 93% of optometrists were willing to examine people with dementia (12) but evidence is lacking on the uptake and quality of vision care.

It is estimated that between 20% and 50% of older people have undetected reduced vision (10) and it is likely that there is significant under-detection and inappropriate management of VI in people with dementia (14, 15, 16). We have run pilot focus groups with optometrists, family members of people with dementia and professional carers, and our results support these findings. More information is needed on VI prevalence in people with dementia, particularly the extent to which problems may be undetected or inadequately managed and the reasons why. This is particularly significant because VI can contribute to other problems (17). Older people with VI are almost twice as likely to have a fall (18) and behavioural and psychological problems in people with dementia can also be exacerbated by poor vision (10). Loss of vision profoundly affects quality of life (10, 19) and increases the relative risk of admission to care homes (3.3 compared to people who are visually intact)(22). Conversely, cognitive impairment improvements have been reported after cataract surgery (20, 21). In summary, clarification on visual deficits in dementia patients is needed more than ever (23).

Need

Health need: Many cases of visual impairment (VI) in elderly people can be either prevented or successfully treated. However, without early detection and correct management some

conditions can lead to blindness. Evans et al (10) concluded that there is overwhelming evidence that a very large proportion of older people do not receive appropriate eye care and that the sight of many of these people could be improved.

Furthermore, behavioural and psychological problems in people with dementia are reduced when VI is prevented or corrected, with a corresponding positive impact on quality of life.

This study will measure the prevalence of visual impairment in older people with dementia, assess whether or not it is higher than in the elderly population in general and identify the proportion of cases that are undetected. Moreover, the qualitative element of the study will employ multiple perspectives to explain why vision problems go undetected in people with dementia, inform practice and lay foundations for further research to address this issue. Increasing the awareness of the need for appropriate eye care among people with dementia, carers and eye care professionals will help to improve equity of care.

Expressed need: Loss of visual function is a major cause of disability and loss of independence. Visual impairment is a risk factor for falls (24). Assessment of visual function is an essential component of a falls risk assessment (25), but upstream interventions to reduce falls risk should also be pursued, and this requires knowledge of the prevalence and associated characteristics of older people with unrecognised visual impairment. Visual impairment can reduce the ability of older people to look after themselves, resulting in a need for personal care (24). However, a very large proportion of older people does not receive appropriate eye care and many of these people could be helped by cataract surgery or appropriate refractive correction (spectacles). Cognitive impairment is one of the factors that hamper the early identification of visual impairment, whilst visual impairment exacerbates behavioural and psychological problems in people with dementia. Mapping the overlap of visual impairment and dementia is therefore a precondition for reducing risks in an ageing population.

Sustained interest and intent: The risk of dementia and many of the conditions that can cause serious visual impairment – cataract, glaucoma, AMD, diabetic retinopathy – increases with age. With the predicted increases in the UK elderly population, the prevalence of eye conditions in people with dementia will inevitably increase. It is therefore essential that early detection is improved to avoid an increase in the number of cases of preventable sight loss and reduce the complications of visual impairment (notably falls, behavioural and psychological problems).

Capacity to generate new knowledge: Overall, the topic of visual impairment in the dementia population has not been well researched, either nationally or internationally and there is a lack of good quality evidence on prevalence, detection rates, barriers to examination, carer awareness, or eye care professionals' ability to provide specific care for this patient group. The outcomes and recommendations from this study will inform practice and lay foundations for further research into all these aspects of the topic.

Organisational focus consistent with HSR mission: In keeping with the remit of the HSR programme, this study is concerned with the quality of eye care services for people with dementia. It will examine issues of access and equity in provision by exploring whether existing mechanisms are adequate for identifying visual impairment in this patient group, identifying and explaining the barriers to eye care for people with dementia. This will inform the development of services that are relevant and appropriate to the needs of individuals, promote effective and efficient use of health services and improve the experience of eye care services for people with dementia and their carers.

As with other HSR projects, a multi-disciplinary team will be involved in the study to ensure that the research questions addressed have relevance to primary and secondary care, to optometrists, ophthalmologists and other eye care professionals, to professional and family carers and service users, the voluntary sector and professional bodies. Methodologically the

team encompasses expertise in a wide range of research methods and the project will employ both quantitative and qualitative approaches.

Generalisable findings and prospects for change: The study will produce generalisable findings by collecting data from a sample from four centres in England selected to ensure a mixture of city, urban and rural settings and to encourage inclusion of people from a range of black and minority ethnic populations. This will ensure that the findings are of value to the NHS management community and NHS commissioners throughout England. The study will offer a number of recommendations on improving access to, and the quality of, eye examinations for people with dementia. However, individual stakeholder organisations may decide to focus on specific recommendations that will complement existing services, in the same way that enhanced eye care services for other patient groups have started to be implemented in recent years. For example, as in the case of people with learning disabilities, commissioners variously decide to focus on training progammes for optometrists to improve their skills in working with people with dementia, or to fund an enhanced fee (over the normal GOS fee) to cover the cost of extended appointment times, or to review the provision of domiciliary services. In our pilot investigations we found that among family carers of people with dementia there was limited awareness of either the entitlement to domiciliary services or the means of accessing them. We also found some accounts that this information was difficult to get from PCTs (which contracted these services at the time) and Optometrists (who are contractually obliged to either provide such services or offer clear information about how such services can be accessed).

Building on existing work: Previous studies have provided estimates of prevalence of visual impairment in the general and elderly populations but insufficient attention has been paid to measuring prevalence in people with dementia, the possibility of under detection, barriers to eye care for this patient group or how to improve services to promote equity and access to services. The proposed study will make a significant contribution to the HSR programme in the dual fields of vision and dementia care. In line with the Dementia Themed Call Specification Document the proposed research will focus on the management and care of people with dementia, focusing on vision problems and seeking to demonstrate how benefits may be achieved which contribute to the well being of people with dementia and how improvements may be made in the organisation and delivery of eye care.

Methods

Design and theoretical framework

A two stage study is planned.
Stage 1 is a cross-sectional study to establish the prevalence of a range of vision problems among people with dementia. These vision problems include: cataract, age related macular degeneration (AMD), glaucoma, diabetic retinopathy and uncorrected refractive error.
Stage 2 is a qualitative study using focus groups and interviews to explore and describe patient, carer and professional perspectives on detection and management of vision problems among people with dementia.

Sampling

The Stage 1 cross sectional study will investigate two groups of people with dementia aged 60-89 years with 385 people in each group. Group 1 will comprise people living at home and Group 2 will comprise people living in care homes. The sample size has been calculated to allow detection of a prevalence of 50% with 5% precision and 95% confidence based on the reported estimated prevalence of VI in the population (5, 26). Subjects will be recruited through Memory Clinics and Old Age Psychiatry clinics in NHS trusts and through general medical practices with the assistance of DeNDRoN and Local Coordinating Research Networks. Additionally, Group 1 subjects will be recruited through Alzheimers Society local groups and Group 2 subjects will be recruited through direct contact with care homes. Where participants are recruited via AS, they will only be recruited from groups of service users for whom a medical diagnosis of dementia has been confirmed through the AS processes. It should also be noted that recruitment through AS is not intended to be the primary route, but rather an additional source of participants to enhance the overall recruitment strategy. BUPA

has offered to support the study but we will also recruit through other care providers to reduce the risk of selection bias. Further subjects for both groups, especially those living at home, can also be recruited through The Outside Clinic, one of the UK's leading providers of domiciliary eye care services. They have informed us that they test approximately 2,500 people with dementia each year (living in their own homes and in care homes).

Strategy: The team is aware that recruitment of people with dementia into research studies is not easy and we have adopted a multilayered approach to recruitment. It is intended that the majority of subjects for the prevalence study will be recruited with the assistance of regional DeNDRoNs and CLRNs.

DeNDRoN is launching the ENRICH research ready-care home network this year and we will make use of this to recruit participants.

Identification procedures

Potential participants with dementia will be identified from their medical records by the direct care team or by DeNDRoN or Local Coordinating Research staff who are frequently embedded in NHS clinics. In addition DeNDRoN maintain case registers of patients with dementia who are willing to participate in research and suitable participants who are on this register will be identified and approached.

Other methods of recruitment will involve posters and notices in NHS clinical areas informing patients that the study is being conducted and giving contact details. Similarly potential patients will be recruited via the Alzheimer's Society; however this recruitment process is external to NHS clinics and thus we will, with written consent from potential dementia participants approach their general practitioner to clarify from their medical records that they meet eligibility for inclusion in the study (e.g. a formal diagnosis of dementia).

We have identified a possibility that a small proportion of the potential participants may already be participating in clinical trials for new pharmaceutical products. As there would be no information about potential interactions between the trial drug and other medications or drugs used during the eye examination (i.e. Tropicamide), we will exclude patients on such trials from this study.

Given that the study requires carer/family member involvement at a number of stages, we will seek to involve only those patients with dementia who have carers or family members. Identification of carers / family members will proceed in tandem with the identification of suitable dementia participants; details of carers / family members are frequently recorded in both primary and secondary care medical records and in DeNDRoN associated patient case registers.

Approach and consent procedures

The initial approach will either be made by direct care team or a member of the DeNDRoN to appraise the participant as well as family members/carers of the study and its remit. This will either be done by direct face to face (for example in clinic), telephone or letter. Participants and family members/carers will then be provided with written information on the study's purpose, methods, risks and burdens, and given a minimum of one week to consider their participation.

Subsequent to this participants and family members/carers will then be contacted by either a DeNDRoN staff member or by a member of the research team (either face to face or by telephone depending on the participant's preference) to determine if a participant and family member/carer is willing be involved in the study. Formal written consent will either be sought then from the patient or just prior to the formal study assessments. In addition, given the involvement of carers / family members in the study (for example carer's views) separate

formal written consent will be sought from the family member/carer for the recording of information provided by them.

Including patients who lack capacity

Ethically and for generalisability of the findings it is important and appropriate that we try to include within the study dementia patients who potentially lack capacity to consent. There is a formal structure supportive of this within the tenets of the Mental Capacity Act (2005) for approaching and including patients without capacity to consent to research participation and we will adhere to these processes and requirements within this study:

- In recognition of the complexities surrounding informed consent and capacity in dementia patients, all research workers involved in the study will undergo formal NIHR Clinical Research Network training in good clinical practice, informed consent, the ethics of consent, and the Mental Capacity Act.
- While the majority of participants will have sufficient capacity to give consent, some will have lower capacity but every endeavour will be made to maximise understanding. Patients who are unable to consent for themselves will be provided with all possible information about the research, tailored to maximise their understanding, with multiple opportunities to ask questions and interact with the researcher to ensure that the most information possible is obtained and retained by them.
- In the case of individuals unable to consent for themselves, a personal consultee (often a family member) identified by agreement with the patient will be asked for their opinion in relation to the potential participant taking part in the study.
- The consultee will be asked to take into account any advance decisions or previously expressed wishes and feelings, and consider the potential participant's best interests. In some instances a carer may have a lasting power of attorney, and may thus potentially be able to give consent on behalf of the person with dementia. Since the precise terms of each Lasting Power of Attorney (LPA) can vary, any consent received in this way will be checked carefully against both ethical guidance and the individual LPA. Staff carrying out such checks will pay close attention to the Mental Capacity Act 2005 guidance document.
- Where an LPA enables a consultee to consent on behalf of a potential participant, the consultee will be given an information sheet with the same information as a patient able to consent for themselves would have received, and be asked to sign a "Consultee Declaration Form" confirming that they
    - have read the information sheet giving details of the study
    - have had the opportunity to ask questions and understand what is involved
    - have given their opinion whether he/she would not object to taking part in the study
    - understand that participation is voluntary and that they can request that the patient is withdrawn from the study at any time without giving any reason and without their medical care or legal rights being affected
    - understand that relevant sections of medical notes may be looked at by the research team and information taken from them for use in this research, or in the monitoring of the research by clinical governance staff
    - understand that information will be held by the research co-ordinators
    - understand that records will be confidential and will be stored securely on systems within the NHS and University systems
    - understand that the GP of the person participating in the study will be informed of their participation in this study; and that the consultee agrees that data relating to the party participating in the study can be used in similar studies.
- It is recognised that patients with dementia often fluctuate in terms of their cognitive function and capacity; research staff will be alert to any signs of distress or unwillingness to continue in the study, formally expressed or otherwise. In these

cases the assessment procedure will be discontinued and the dementia patient will be withdrawn from the study.

In Stage 2 a total of 12 focus groups will be held, comprising three groups in each of the four centres (see Setting and Context) and three groups will focus separately on eye care professionals (community and hospital optometrists, ophthalmologists, dispensing opticians); professional carers (care home staff, day care staff, community support workers) and family carers. This reflects the recommendation that a minimum of three focus groups is conducted within any population in a study (27).

Additionally, individual face-to-face interviews will be sought with people with dementia who are able to consent to interview. Interviews will continue until no new data is being generated. Qualitative studies usually achieve saturation with 30 subjects (28) and this is the number envisaged in this study although recruitment will continue beyond 30 subjects if necessary.

Setting/ context

In Stage 1, subjects will be randomly recruited from multiple sites in four centres in England: London, Thames Valley , East Anglia and the North East to reflect demographic differences such as city, urban and rural settings and to encourage inclusion of people from a range of black and minority ethnic populations. We will recruit from multiple sites within each region. Regional Network Coordinators were contacted at the proposal development stage; they did an initial canvas for support which revealed widespread interest from local PIs and feedback that the study would be likely to be popular with patients and carers given the practical and widespread applicability of the topic.

Difficulties in recruiting people from black and minority ethnic groups were addressed in feedback to reviewers following submission of the full proposal. Our strategy aims to recruit subjects from a range of geographic areas to include a demographic mix of inner city, urban and rural areas. We will purposely seek to recruit subjects from BME groups in city populations where the ethnic populations are greatest e.g. London (North Thames), Leicester (Thames Valley). We have also approached the Primary Care Research Network in Central England (PCRN-CE) which has offered to approach GPs across their area to identify BME patients who could be invited to participate in the study.

The Stage 2 focus groups and individual face-to-face interviews with people with dementia will also be held in the same four centres.

Data collection

Stage 1: The subject will have a full optometric examination in line with requirements of the GOS sight test for people aged 60 years and over and the College of Optometrists' guideline CO4: *Examining the patient with dementia or other acquired cognitive impairment*.

During the examination of study patients the over-riding principle is that the optometrist should adopt a flexible approach throughout. The examination will be performed according to the cognitive and physical abilities of the patient, with the emphasis on objective assessments and omitting tests (both objective and subjective) as required. This approach is consistent with current College of Optometrists professional guidance on examining patients with dementia. When patients are to be examined in care homes, or in their own homes, appropriate advance warning of the optometrist’s visit will be given to patients and carers.

On arrival at the care home/private home the optometrist will introduce themselves to the patient again, explaining again who they are and why they are there. The optometrist will then set up her/his equipment in the room allocated for the eye test (care home) or in the most appropriate available room if the test is to be carried out in the patient’s own home. Where

there is a choice of room for the eye test, the ability to achieve dim illumination will be a major factor in the final selection.

Prior to commencing the eye test, participants will be asked if there are any tasks that they find particularly difficult. Where a participant is unable to respond appropriately advice will be taken from carers and/or care home staff as to the cognitive and other abilities of the patient.

The tests will normally be conducted in the following order, though flexibility is the watchword here and the order of tests can be adapted as required to suit the individual patient.

1. History and symptoms will be obtained from the carer and/or from the patient. When examined in a care home the optometrist will request access to the patient's care record (or ask staff to provide information from the record), from which information relating to general and ocular health can be obtained. Also, where necessary, input will be sought from carer(s) or care home staff regarding the patient's history and symptoms.

2. Vision and Visual Acuity will be recorded using the Thomson Test Chart 2000 Lite, which allows the selection of letters or symbols which are most appropriate to the cognitive abilities of the patient. Test Chart 2000 Lite allows the presentation of standard LogMAR acuity tests, Snellen letters, Tumbling Es, Landolt Cs, and symbols. Furthermore, the choice of chart and size of letters/symbols presented to the patient can be altered at the touch of a button. The chart can be used at any test distance, so is ideal for domiciliary tests in rooms of varying dimensions.

It is estimated (based on consultation with optometrists with experience of working with people with dementia through the UK's leading provider of domiciliary eye care services) that at least 60% of our patients will be able to complete this Visual Acuity test, the results of which will allow us to identify the presence of visual impairment.

3. Binocular function will be assessed using the cover test and by testing ocular motility. In the cover test the optometrist observes the patient's eyes while one eye is covered in turn and then uncovered. The test allows for the detection of squint (strabismus) and other binocular vision anomalies. The cover test is carried out for both distance and near viewing, with the patient fixating a target. A range of fixation targets can be used on Test Chart 2000 in order to capture and hold the attention of the patient for tests that require steady eye and head position. For the motility test, which checks for any over- or under-action of the extra-ocular muscles, the patient is required to follow a moving light with their eyes while keeping their head still. Both cover test and motility should be possible for at least 60% of our patients. These tests are included in the eye examination but are not part of the battery of tests directly relevant to the research study.

4. Pupil reactions: The integrity of the pupillary pathways is assessed by shining a torch into each of the patient's eyes in turn. This objective test should be possible on the vast majority of patients. Testing pupil reactions is included in the eye examination but is not part of the battery of tests directly relevant to the study.

5. The intraocular pressures (IOPs) will be measured using the iCare tonometer. This instrument is well accepted by patients. Although the test involves contact between a sterile probe and the patient's cornea, this contact is minimal and iCare tonometry does not require the use of a local anaesthetic. Tonometry is an objective measurement during which the only requirement from the patient is that they keep their eyes open and maintain reasonably steady fixation. The iCare tonometer is widely used in domiciliary testing by optometrists and acceptable agreement with the gold standard Goldmann Applanation Tonometer has been established in recent research (Jorge et al 2010).
It is estimated that tonometry will be possible on 90% of our patients and the results will contribute to the identification of glaucoma suspects and ocular hypertensives (patients with elevated IOP but no other signs of glaucoma).

6. The objective determination of refractive error (retinoscopy) will allow the strength of the patient's spectacle prescription to be determined. Retinoscopy is a technique which is used by optometrists in almost all eye examinations, and is attempted in all domiciliary tests. For retinoscopy the patient is required only to look into the distance at a light or other fixation target. The retinoscope beam of light is directed into the patient's eye and a proportion of this light is reflected from the back of the patient's eye and can be viewed in the patient's pupil (the retinoscope reflex). While viewing the reflex in the patient's pupil the optometrist uses lenses to modify the appearance of this reflex until an end point is reached (reversal).

The strength of lenses that produce the reversal end point allows the optometrist to measure the patient's refractive error. During retinoscopy the lenses will either be placed in a trial frame worn by the patient or, where necessary if poor co-operation dictates, be held by the optometrist in front of the patient's eyes.

Wherever possible, this retinoscopy result will be modified subjectively with the patient reading letters or symbols presented on the test chart through different lenses selected by the optometrist in order to refine the retinoscopy result. The patient's Visual Acuity with the final spectacle prescription found by retinoscopy or subjective examination will be recorded. It is estimated that retinoscopy will be possible on 70% of our patients, with subjective refinement possible in most of these (50% of the total sample). These results will contribute to the identification of uncorrected refractive error and visual impairment.

7. Posterior eye examination: At this stage in the test the patient's pupils will normally be dilated using tropicamide eye drops to facilitate the examination of the eye's structures behind the iris, notably the lens, the retina and other back of the eye structures. Prior to pupillary dilation, the likelihood of the pupil dilation provoking an acute angle closure glaucoma (ACG) attack will be assessed using the pen light test for anterior chamber depth estimation (Elliott 2007). The risk of provoking an acute ACG attack with tropicamide is very low (Pandit and Taylor 2000, report zero cases of ACG in almost 4000 dilations). However, patients judged at risk of an ACG attack will not be dilated and will be examined through undilated pupils.

The tropicamide drops take approximately 15 – 20 minutes to produce a sufficiently dilated pupil. During this time the patient can have a break, if required, the examiner can complete the MMSE if necessary, the strength of any current glasses can be measured using a focimeter, and the external eyes can be examined using the ophthalmoscope. Once the pupils are fully dilated the examination of each eye follows using a direct hand held ophthalmoscope. The patient needs only to keep their eyes open and, if possible, to follow instructions as to where to direct their gaze. It is estimated that direct ophthalmoscopy will be possible on 85% of our patients and the results will contribute to the identification of cataract, AMD, diabetic retinopathy and glaucoma suspects.

As a further check on the possibility of a dilation-induced acute ACG attack, post-dilation IOPs will be measured using the iCare tonometer. A significant increase in IOP could be an indicator of a pending ACG attack and if this is suspected the optometrist will remain for a further hour and continue to monitor the patient.

8. Visual fields: If possible the patient's central visual fields will be plotted. This is by far the most demanding of the tests attempted in this eye examination and will not be possible in many of the patients. The visual field test used will be a supra-threshold test (faster and less confusing than threshold testing) using the Oculus Easyfield, or FDT (Frequency Doubling Technology) or equivalent perimeter. It is estimated that visual field testing will be possible on only 20% of our patients. The results will contribute to the identification of glaucoma suspects.

9. Quality of Life: In cases where visual impairment has been detected or treatable conditions have been undetected or untreated we will measure the patient's quality of life using an

established tool (VISQOL, EQ-5D or QoL-AD) and ask our experts on the Steering Group (ophthalmologist and old age psychiatrist) to offer a clinical view which will be added to the data and included in the study analysis.

10. Conclusion: The examination will conclude with verbal and written advice being passed on to patient and/or carer. This will include advice on any referral required, on the use of new spectacles, and on the recommended date of the patient's next eye examination. The carer and/or patient will be given a leaflet explaining the effects of the tropicamide drops, including the symptoms and signs of an ACG attack and advice on the action to take in the unlikely event of this occurring.

If patient cooperation is poor the optometrist will move step 7 forward in the eye examination. This will allow the optometrist to focus on ophthalmoscopy through dilated pupils, which is the key test for detection of eye disease and which does not require much patient co-operation. Carer's views will be sought on the extent to which the subject's ability to cooperate with the examination reflected his or her usual state. This will be noted on the record card.

Based on their experience with the patient, the optometrist will record how accurate the results from each patient are likely to be.

Participating optometrists will receive training to ensure an optimal standardised approach to examination. This pre-study training will include guidance on the ethical issues associated with research on subjects with dementia.

Stage 2: Data will be collected from focus groups of eye care professionals, family carers and professional (paid) carers and interviews with people with dementia. The focus group question schedule will be semi structured and cover participants' understanding of eye care for people with dementia; expectations of the eye examination; experience of eye examination and eye care of people with dementia; barriers encountered; and facilitators and strategies to improve eye care. Data obtained in each interview will depend on the individual's ability to recall, communicate and comprehend and will vary according to the degree of dementia.

Data analysis

Stage 1 – prevalence, along with their 95% confidence intervals, of VI due to refractive error, cataract, age-related macular degeneration, glaucoma and diabetic retinopathy will be established. These Confidence Intervals will be used to compare the prevalence of the VIs with published figures in the general population. Prevalence levels between people living at home and people living in care homes will be compared using tests for two independent proportions. Proportions of both previously undetected cases and detected but inappropriately managed cases will also be compared between people living at home and in care homes.

Missing data:

Our primary research objective was to measure the prevalence of a range of vision problems in a generic sample of people with dementia aged 60 to 89 years. The study is adequately powered to achieve this objective. The use of two groups of subjects is mainly to allow us to identify any differences in the level of undetected or inappropriately managed visual impairment between the two groups. This will inform Stage 2 of our study, in which we will investigate the reasons for any undetected or inappropriately managed visual impairment.

Our sample size of 385 subjects in each group is based on an estimated prevalence of 50% with 5% precision and 95% confidence. This figure of 50% was the highest prevalence quoted in the literature for one of our target conditions. If the prevalence of a condition is either greater than or less than 50% then the study will require a sample size smaller than 385. We had anticipated that in a study of this nature there would be some missing data for each of the optometric tests as some of the participants/patients will be unable to perform them. There is no published data on the percentage of those with dementia who will be able to perform successfully individual elements of an eye examination. In the absence of published data we

took the view when writing our proposal that even if as few as 50% of subjects were able to complete a particular test with a prevalence of 50% (the worst case analysis) we would still have data from 385 subjects (50% of our total of 770), which is sufficient to generate a reliable estimate of the overall prevalence for the condition in a generic sample of patients with dementia.

Following the request for more detail on the impact of missing data we have consulted with a number of optometrists with extensive experience of eye examinations conducted on patients with dementia. Based on their responses we have quoted in Section 2 above (Testing people with dementia) estimates for the percentage of patients with dementia who are likely to be able to complete each test. The lowest percentage they estimate is 60%, compared with our worst case figure of 50% which was the figure used for our sample size calculation. Furthermore, these estimates suggest that, not only does our study have sufficient power to be able to generate a reliable generic figure for prevalence in dementia for each of our target conditions, but also that we should have sample sizes that are sufficiently large to allow statistical testing of differences in prevalence between our two groups (care home residents versus those living at home) for at least two thirds of the target conditions.

In the absence of published data on the likelihood of a patient with dementia being able to complete each of the tests comprising a full eye examination, an important secondary outcome of our study will be the determination and dissemination of estimates for the percentages of patients with dementia likely to be able to perform each test successfully. The data that we plan to collect beyond that derived from the eye examination (Carer data/ responses; Activities of Daly Living data; Quality of Life data etc.) will provide valuable information for the study, and these data will be gained even from participants who are unable to complete the eye examination – and may be particularly useful to have for this group. Understanding (and having evidence of) which elements of vision testing and eye health examinations are problematic and some of the characteristics of the individuals for whom these elements of an over all eye examinations are more likely to be difficult is an important piece of information in itself.

Stage 2 – Data collected in the focus groups and interviews will be audio recorded and the recordings will be transcribed. The transcripts will be analysed using Framework Analysis (29) to identify recurring themes. These themes will include, but not be limited to, experiences of eye care, reasons for under-detection and inappropriate management of VI, and recommendations for practice and future research. Data analysis will be undertaken independently by two of the research team, then compared for inter rater reliability.

Contribution to collective research effort and research utilisation
Prior to publication of the summary report, the findings and recommendations will be circulated to stakeholders, including participants in Stage 2 focus groups, for review and their contributions. Following publication of the summary report, papers will be submitted for publication in relevant professional and peer reviewed journals.

The College of Optometrists will use the study findings to update its guidelines on examining people with dementia (2). The College will also incorporate the findings into its programme for continuing education and training of optometrists.

The Alzheimer's Society and Thomas Pocklington Trust will disseminate the study findings through their networks and on their websites, and will develop guidelines for people with dementia, carers and health care professionals.

Pocklington is committed to the dissemination of research findings and their translation into forms that can affect policy and practice. We make findings freely available through publications, training and workshops. Our publications routinely reach over 2000 people / organisations involved in research, policy and practice affecting people with sight loss.

Both Pocklington and Alzheimer's Society are members of the Vision 2020 UK Dementia and Sight Loss Interest Group and can use its contact with policy makers and practitioners to promote and disseminate findings.

Plan of investigation and timetable

April - September 2012 : (between notification of successful application and study start date)

- Advertise and appoint the Project Manager, Researcher and Research Administrator
- Confirm Research Sites and Principal Investigators at research sites through DeNDRoN LRNs and CLRNs
- Design Participant Information material, consent forms and data collection forms
- Apply for and secure NHS Ethical approval
- Apply for NHS permissions using NIHR CSP (Coordinated System for gaining NHS Permission)
- Identify and recruit research optometrists

N.B. This work will be carried out by the Lead Applicant using College of Optometrists' resources and co-applicants' support as detailed in the application.

October 2012 - April2014: Stage 1

- October 2012: train research optometrists
- November 2012: pilot procedures
- January – December 2013 recruit subjects and data collection
- January – April 2013: data analysis

February 2013 - 2 – April 2014: Stage 2

- February 2013: arrange focus group dates and venues
- March – September 2013: recruit participants for Carer focus groups
- June – September 2013: recruit participants for Eye Care Professionals' focus groups
- October – November 2013: run focus groups (x 12)
- March – November 2013: recruit and conduct interviews with people with dementia (x30)
- November 2013 – April 2014; focus group and interview data analysis

May – September 2014: reporting and dissemination

Approval by ethics committees

Ethical approval will be sought through the NHS Research Ethics process. Site specific NHS R&D approval will be required at all sites involved in recruiting subjects. Application will be made via the NIHR Coordinated Systems for gaining NHS Permission facilitated through DeNDRoN.

Project Management

Mike Bowen (MB), Lead Applicant and Director of Research at the College of Optometrists will have overall management responsibility for the project. He will line manage the Project Manager, Researcher, Administrator and College staff involved in supporting the study.

A Management Group will be established to operationalise the study and ensure that the project progresses according to the proposal. The Management Group will comprise MB, the Project Manager, Researcher, Professor David Edgar (DE) and Dr Beverley Hancock (BH). DE will lead on the Stage 1 prevalence study and BH will lead on the Stage 2 qualitative study.

The Management Group will report to a Steering Group comprised of all project applicants, the Project Manager, Researcher, additional service user representatives and one of the research optometrists collecting data in Stage 1. The Steering Group will meet six times a year and communicate via email in-between meetings to oversee the project and provide ongoing advice to the Management Group.

The Project Manager and Researcher will be responsible for liaising with Principal Investigators (PIs) at research sites, recruiting subjects and optometrists who will collect data in Stage 1. The composition of the Steering Group is such that at least one member has pre-existing links with each of the areas proposed, and one member of the Steering Group will have a role supporting the Project Manager and Researcher in each of the four geographic areas.

Public contributor/public involvement
This project has benefitted from public involvement from its genesis. It was presented at a workshop facilitated by the Alzheimer's Society on May 5th 2011, a workshop specifically organised to provide public involvement in research. 40 volunteers attended the meeting and 9 groups of volunteers had expressed an interest in the project based on reading the original abstract. All groups were strongly supportive of our research proposal. Public involvement will continue throughout the project.

The aims of active involvement in the project are:

- Ensuring that the research topic is relevant to the experiences and needs of carers and patients
- Ensuring that the outcomes measured are appropriate to carers and patients
- To benefit at all stages of the project from the perspective of carers and patients
- Contributing to development of Participant Information materials thereby assisting with recruitment of subjects
- Improve the relevance of results and recommendations

Susan Maskell: Sue is an experienced research volunteer having been a member of the Alzheimer's Society Research Network for 10 years. She cared for her mother who had dementia. Ms Maskell is a co-applicant and has a key role to play in informing the study design, drafting participant information resources, and aiding recruitment. Ms Maskell is available to discuss the research with patients and carers who have questions to ask regarding the research. As a member of the Steering Group Ms Maskell will contribute to all aspects of the study as it evolves. Another three research volunteers have been identified to contribute to the Steering Group.

Thomas Pocklington Trust is a sight loss charity providing operational services for people with sight loss and commissioning research. It is active across the charitable sight loss sector. Through its role in the project it will ensure that findings are communicated across the sector and that connections made across the sector work to inform relevant policy and practice and to support practitioners.

Expertise and justification of support
Mike Bowen, Lead Applicant. As Director of Research at the College of Optometrists, he will have overall management responsibility for the project. As a member of the College's Senior Team he will be able to utilise appropriate support from other College directorates, the Optometric Research Network and College Council members as required.
Professor David Edgar, Professor of Clinical Optometry at City University London, will be Lead researcher on Stage 1 and provide clinical leadership for the Project Manager, Researcher and research optometrists. He has vast experience in primary care optometric research, primarily through his management of EyeNET, the NHS funded primary care eye research network based in the London area, which ran for more than 10 years.
Dr Beverley Hancock, Research Adviser to the College of Optometrists, will lead on Stage 2 qualitative research. She has 20 years experience of qualitative research working with universities and NHS organisations on a wide range of topics including mental health and sensitive areas such as cancer, erectile dysfunction, and HIV and has been involved in research capacity building across primary care professions since 1995.
Sarah Buchanan, is Research Director at Thomas Pocklington Trust and is responsible for commissioning and managing a small programme of public health, social and qualitative research and the dissemination and application of findings. Pocklington's work focuses on the

experience, prevention, alleviation and cure of sight loss. A policy of progressive and cumulative research has laid foundations for work with sight loss and dementia interests to increase awareness of the concurrence of dementia and sight loss and work to ensure that both conditions are addressed in policy and practice.

Dr M Sayeed Haque, Lecturer in medical statistics at the University of Birmingham has over 15 years of research experience in medical research. His topics of interest are mental health, primary care, ophthalmology and dentistry. Dr Haque will advise on and assist with the design of data collection tools, sampling and data analysis in Stage 1.

Dr James Pickett, Research Grants Officer at Alzheimer's Society, will co-ordinate public and patient involvement and dissemination of research outcomes and can draw on the wealth of experience in the Society. The Society also has a number of dissemination avenues and its resources are directly accessed by people with dementia, which will be utilised during the later stages of this proposal.

Susan Maskell, has been a member of the Alzheimer's Research Network for ten years. Susan had the experience of caring for someone with both sight problems and dementia. She cared for her mother at home for six years and was closely involved in her care in a nursing home for six years. Her mother had been visually impaired and registered blind. Susan had the opportunity to witness the assessment and treatment of her mother's problems in a variety of settings, the experience of which should enable her to contribute substantially to the proposed research; she has concerns about the accuracy of visual assessment given the communication problems that dementia presents.

Dr Michael Clarke, Reader in Ophthalmology and Consultant Ophthalmologist at the Royal Infirmary Newcastle is also Director of the Vision theme for the Newcastle Biomedical research Centre for Ageing. His research interest in this field is the relationship between ocular and cerebral pathology in visual symptoms experienced by elderly patients, particularly those with early dementia. Dr Clarke will provide ophthalmological input to every aspect of the project, notably in relation to the training of the research optometrists and in the dissemination of outcomes.

Professor Steve Iliffe, is Professor of Primary Care for Older People, University College London. His research interests cover many aspects of the care of older people and he has published widely in the field of dementia. Professor Iliffe will provide primary care input throughout the project, with particular emphasis on methodological advice and recruitment of subjects.

Dr John-Paul Taylor, is Wellcome Intermediate Clinical Fellow and Senior Clinical Lecturer at Newcastle University, and an Honorary Consultant in Old Age Psychiatry with Northumbria Tyne and Wear NHS Foundation Trust. His research interests span many aspects of vision in dementia. Dr Taylor brings to the research team invaluable experience in clinical research on older people with dementia. This expertise will be utilised at every stage of the project.

Planned or active related research grants

Prof Iliffe is CI for an NIHR funded grant developing and testing evidence-based interventions in dementia in the community, and for an HTA funded multicentre cluster RCT comparing community with home-based exercise in over 65s. He is a co-applicant in the MRC funded project developing the Crucible Centre at UCL which brings together research groups across UCL to tackle the problems associated with life-long health and well-being. He is also a co-applicant for the IMPACT study into palliative care in dementia and cancer in Europe funded by the European Commission, and for another MRC grant to carry out a multi-dimensional health risk appraisal for older people.

Dr Clarke is undertaking a pilot clinical trial of surgery for strabismus in children (HTA 09/01/20) and is co-supervisor with Dr Taylor of an NIHR funded PhD student working on cognitive impairment in patients with cataract.

Dr Taylor is PI on a study investigating attentional function and cognitive fluctuations in Lewy body disease (funded as part of a Wellcome Intermediate Clinical Fellowship). He is also primary supervisor for an Alzheimer`s Research UK PhD student working on the neurophysiological basis of cognitive fluctuations in Lewy body dementia.

Alzheimer's Society is currently engaged with a range of applications across the NIHR programme streams in providing dissemination and PPI support.

The Pocklington Trust are currently a co-applicant, with Sarah Buchanan as the link, in a RfPB project (led by Manchester university) which is a pilot study to promote adherence to two interventions to prevent falls in older people with visual impairment.

The portfolio of clinical research listed above informs and complements the current proposal. The contributions of Prof Iliffe, Dr Clarke and Dr Taylor to the research in this submission are predominantly advisory, so are fully compatible with their present commitments and should not detract from their contribution to the work associated with current grants.

History of past or existing NIHR programme research

NIHR programme grant: Changing practice in dementia care in the community: developing and testing evidence based interventions, from timely diagnosis to end of life care (CI Prof Iliffe) has been allowed a no-cost extension for 6 months on one of its five projects.

NIHR Multi-centre cluster randomised trial comparing a community group exercise programme with home based exercise with usual care for over 65s in primary care (CI Prof Iliffe) had a funded 6 months extension.

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