The need to identify patients with dementia and our novel approach

The Government's National Dementia Strategy makes it a priority for everyone with dementia to receive a timely diagnosis[1]. However, **the majority of people in the UK with dementia never receive a diagnosis**[2] and there is considerable regional variation in diagnostic rates (see Figure 1). To address this, Clinical Commissioning Groups in England committed to increase the rate of diagnosis to 66% by the end of March 2015, though that target was not met[3]. Diagnosis is more likely in people who have moderate or severe dementia,[4] which is easier to detect, but many of the benefits of diagnosis, such as being able to plan ahead and be involved in decision-making, have been lost by this stage[5]. New treatments such as solanezumab are being developed by Eli Lilly and other companies that may slow dementia's rate of progression if it is caught early enough. Furthermore most older adults say they would prefer to know if they had dementia[5,6] and the majority of people diagnosed with dementia also state that it is better to know[7,8]. Supporting a more effective route to diagnosis has been identified by the James Lind Alliance as one of the top priorities for dementia research[10].

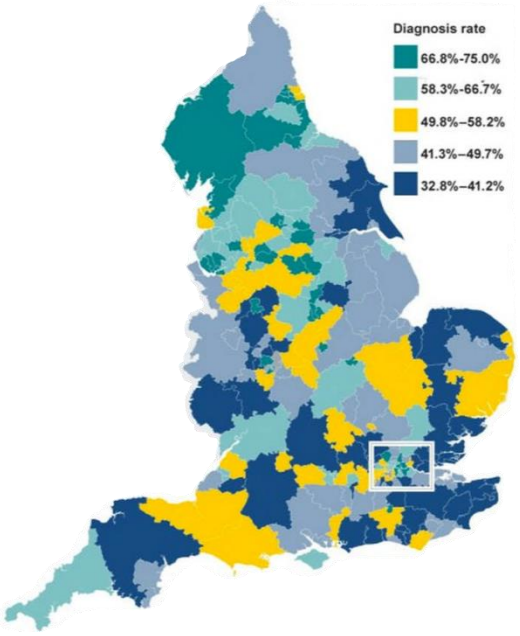


Figure 1. Marked regional variation across England in the proportion of people with dementia currently diagnosed. (Source: Department of Health)

Barriers to the identification of dementia include the failure of general practitioners (GPs) to recognize dementia symptoms and respond appropriately in the limited time available particularly when patients may be attending a consultation for other health problems[4,9]. NICE guidelines recommend GPs employ brief cognitive assessments such as the widely used Mini-Mental State Examination (MMSE) to assess the memory and thinking of patients they suspect may have dementia[11]. However, GPs are often uncertain about when to assess patients in this way, and this approach is likely to result in considerable misclassification.

Computerized decision support systems have been successfully used to improve the detection of a range of other chronic conditions by enhancing clinical judgement. For example, Co-Investigator William Hamilton is a practicing GP and Professor of Primary Care Diagnostics who has developed software for cancer identification. This was popular with GPs and improved diagnostic rates by alerting them in real time to patients with a concerning combination of symptoms[12]. Professor Hamilton's success with cancer diagnosis inspired Dr Llewellyn to investigate whether a similar approach could be adopted to improve the diagnostic pathway for dementia.

As a first step we investigated whether we could improve the accuracy of brief cognitive assessments by taking into account a wider range of patient characteristics. We reasoned that this would more effectively mimic clinical decision making in the real world, where test results are interpreted with caution through a nuanced and holistic perspective. Indeed, NICE guidelines recommend clinical judgement is used in this way when attempting to identify

patients with dementia[11]. Using data from the Aging, Demographics and Memory Study (ADAMS) we analysed 800 older adults to investigate whether combining brief cognitive assessment results with additional clinical information (including sociodemographics and clinical characteristics such as stroke history) would result in improved dementia classification[13]. When we applied the widely used MMSE cut point of <24 over a fifth of older adults were misclassified: 20% appeared to have dementia when in fact they did not (false positives), and 2% had dementia but were missed (false negatives). In practice this would result in a substantial proportion of patients without dementia receiving unnecessary, costly, and potentially distressing further investigations. However, when MMSE results were combined with 10 other patient characteristics there was a large and statistically significant improvement in accuracy ($p<0.001$ for a change in the ROC area). For example, when a cut point of ≥50% is applied to the predicted probability of dementia, **the proportion of older adults misclassified drops from 22% to 6%**. This was very encouraging and provided us with proof of principle that using a wider range of carefully weighted patient characteristics should result in a substantial improvement in the identification of patients with dementia.

No evidence-based computerized decision support system currently exists to enhance the identification of dementia, although a recent review emphasizes the potential of this approach to improve patient outcomes and reduce costs[14]. We recently conducted two focus groups with people with dementia and carers and three focus groups with clinicians: in all the groups, participants agreed this approach is likely to be both acceptable and feasible. Research and Knowledge Transfer at the University of Exeter has therefore invested £15k to allow us to develop a prototype smartphone app which we can then refine and update with ongoing input from patients and clinicians. Similarly the University of Exeter Medical School has committed to providing £15k match funding to support a PhD researcher to refine our predictive algorithms for the timely detection of dementia.

Over the following pages we outline different ways in which the Halpin Charitable Trust could support our programme of research to enhance the diagnostic pathway for dementia.

Option 1

Enhancing the diagnostic pathway for dementia: The DECODE project

This is the most comprehensive in scope and would make the greatest difference to our group and the pace of progress we're able to achieve.

Overarching aim: To develop a computerized decision support system to enhance the timely identification of dementia

Specific objectives

1. To refine and validate our algorithms that combine clinical characteristics to identify dementia more accurately
2. To establish which brief cognitive assessments clinicians should use when attempting to identify patients with dementia
3. To refine our smartphone-based computerized decision support system.

Methods

Our research design is based upon a literature review of factors influencing the effectiveness of computerized decision support systems[15], our focus groups with people with dementia and their carers, ongoing consultation with practicing clinicians, and advice from the National Institute for Health Research (NIHR) Research Design Service. We will develop a dementia identification computerized decision support system (DECODE) using an iterative process supported by a multidisciplinary expert panel incorporating two GPs, a neurologist, a statistician, a decision-making specialist, and a patient representative.

Work Package 1: Refining and validating our dementia identification algorithms

Data from several existing studies will be used to derive and validate the DECODE algorithms based upon patient characteristic combinations that most strongly and consistently increase the probability of dementia. This follows on from Janice Ranson's prize-winning MSc project, which was instigated and supervised by Dr David Llewellyn, and forms the basis for Janice to study for her PhD with our group.

Study populations: We have data for 800 older adults from the ADAMS study (preliminary results above), and 25,000 older adults from the National Alzheimer's Coordinating Centre (NACC). We have also negotiated access to data for 1,600 older adults from the Hellenic Longitudinal Investigation of Aging and Diet (HELIAD), and 8,900 older adults from the Canadian Study of Health and Ageing (CSHA). These large well-designed studies will allow us to validate the weighting given to each dementia status predictor across different populations. Inclusion criteria for the cohort studies were: (1) large studies of adults aged 65+ years, (2) incorporating a wide range of clinically relevant patient characteristics that are complementary to other included studies (3) incorporating at least one widely recommended brief cognitive assessment, and (4) including adjudicated dementia status diagnosed according to international criteria (e.g. DSM). The Principal Investigator, Dr David

Llewellyn, is very experienced in this kind of research and has already published numerous studies on the risk factors, pathologies and functional consequences of dementia.

Data analysis: We will adopt a Bayesian approach to model development that has been used previously[16]:

1. Markov Chain Monte Carlo (MCMC) methods will be used to indicate which predictors should be included in the final model. This approach incorporates previous knowledge about each potential predictor and iteratively selects a robust predictive model which represents the best fit to the data. Bayesian approaches have previously proven to be superior to conventional approaches such as stepwise logistic regression[17].
2. The final Bayesian logistic regression model from step 1 can then be used as the basis for estimating each individual patient's dementia probability.

Although the Bayesian model development process optimizes model fit by design, we will also evaluate it using the Hosmer-Lemeshow goodness-of-fit test within deciles of the total sample in each study[18]. We will assess discriminatory power by calculating the receiver operating characteristic (ROC) area under the curve *c* statistic (our preliminary ADAMS analyses provide compelling evidence that we are likely to achieve excellent discrimination [*c* statistic = 0.98])[19]. We will then evaluate whether this represents an improvement over a more straightforward model by comparing model fit with predictions based upon logistic regression with variables selected using a confidence interval approach[17]. Analyses will be performed using specialized statistical software (R and STATA).

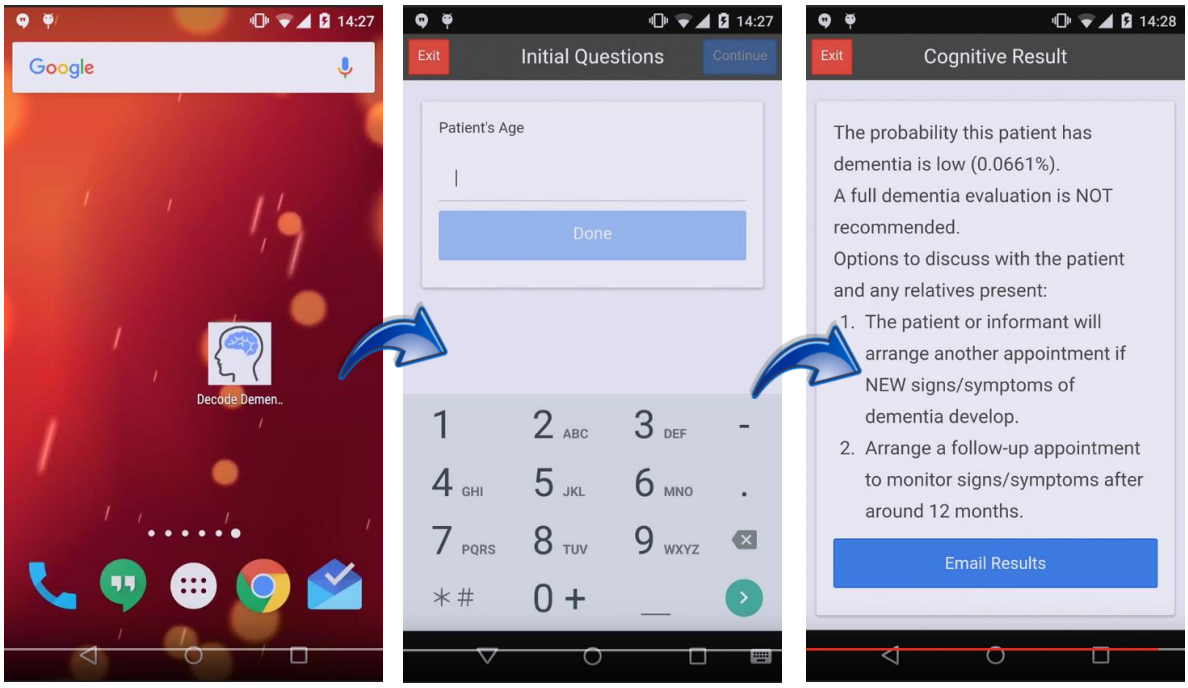
Work Package 2: Comparing the diagnostic accuracy of brief cognitive assessments

Clinicians are recommended to use a brief cognitive assessment with patients with suspected dementia but different organizations, charities and NICE guidelines all recommend different tests. We can develop DECODE algorithms to enhance the use of any of these tests but it would be very useful to improve our understanding of which of these tests is most accurate, and therefore most appropriate for clinical use. A recent systematic review of the literature highlights the lack of diagnostic accuracy studies for tests other than the widely used MMSE[20]. However, the MMSE recently became a proprietary test and is no longer recommended as it is not free for clinical use. The problem is that few other tests have been adequately evaluated and there is a clear need for diagnostic accuracy studies to establish which of these tests is most accurate. We have obtained data from the ADAMS and NACC studies for four of these alternative tests (the MoCA, mTICS, Mini-Cog, MIS) which we can compare to each other, and to the MMSE which acts as a reference standard for minimum accuracy. This will form the basis for a publication which will inform future guidelines for clinicians about which of these tests to use. Postdoctoral researcher Dr Ela Kuzma will perform these analyses using specialized software which will allow her to generate diagnostic test accuracy statistics (such as sensitivity, specificity and positive and negative predictive values). We can also refine the DECODE algorithms at this point by encouraging clinicians to use the algorithms developed for the most accurate of these tests (and by providing us with an academic publication to justify this and provide further information).

Work Package 3: Refining our computerized decision support system

With the support of Research and Knowledge Transfer at the University of Exeter we have begun to develop a prototype smartphone app which provides a practical way for busy clinicians to assess patients in a more targeted and evidence-based way. By working with a professional development company (Natural Apptitude), patients and their families, and clinicians we will continue to improve the appearance, content and usability of the app. The first working prototype of the app is nearing completion, and screenshots can be seen in the box below:

Screenshots of our prototype DECODE app in use



The DECODE logo as it appears on an Android phone

Clinician enters patient characteristics and test results as appropriate

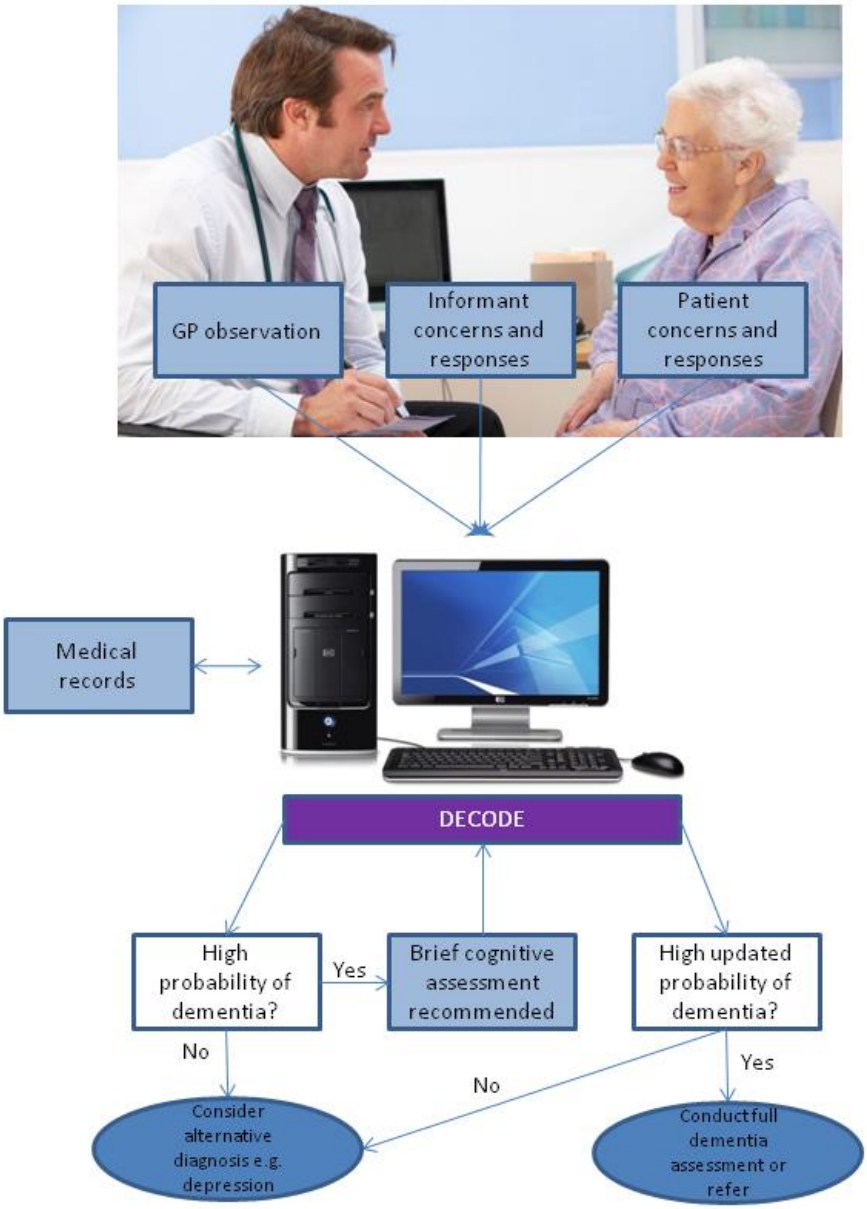
Personalized report generated with the option of emailing a summary

The next step in the development of the DECODE app will be to pilot it with around 15 clinicians who were not involved in the initial app development. These clinicians will come from a range of different specialties that commonly encounter older adults who may have dementia (e.g. GPs, psychiatrists, geriatricians and neurologists). Clinicians will use the app as if they were assessing patients in real time, and will enter patient characteristics based upon 12 case studies/vignettes that we have developed using anonymised real patient data. Dr Ela Kuzma will use cognitive interviewing techniques (a combination of 'think aloud' and 'verbal probing') to elicit information about how the clinicians are using the app and identify confusing or challenging aspects that could be improved. These interviews will be recorded at the time and later transcribed for analysis. After they have used the app the clinicians will then complete a structured questionnaire to rate different aspects of the design and content using rating scales and give any additional feedback using free text boxes. Dr Kuzma will

then analyze these findings and make recommendations for further improvement to the expert advisory panel. Following discussion, this will then be fed back to the app development company to be incorporated in future versions.

Potential impact

Because we recognise that the impact of new discoveries is often dependent on how much thought has been given to their ultimate dissemination and implementation long before they are ready to be applied, co-applicant Dr Iain Lang will consult on these issues from the outset. At the end of the project we will apply for further funding from the National Institute for Health Research (NIHR) to establish whether **DECODE improves diagnostic rates, reduces costs and improves patient outcomes**. We will also apply for funding to develop different versions (e.g. web-based), and develop videos, case studies and other training materials to include on a DECODE website. Our long-term ambition is to embed DECODE within the software used by clinicians working in the NHS and further afield (see illustrative figure below). This has previously been achieved for other conditions including cancer (by Co-Investigator William Hamilton) and would be even more efficient as it would take advantage of existing medical records, thus streamlining the process. DECODE could run in real time in the background and alert clinicians when a patients' symptoms may indicate dementia, and then guide them through a series of initial investigations as appropriate.



The project team

Dr David Llewellyn is a Senior Research Fellow in Clinical Epidemiology with extensive dementia expertise, and takes overall responsibility for study management. Professor William Hamilton is a practicing clinician with expertise in primary care diagnostics and computerized assessment. Dr Daniel Williamson will act as the study's statistician, and has particular expertise in Bayesian modelling. Dr Ela Kuzma is the named postdoctoral researcher on the project with expertise in data analysis and cognitive interviewing. Dr Iain Lang is a consultant in public health and NIHR Knowledge Mobilisation Research Fellow and will oversee the implementation and dissemination aspects of DECODE.

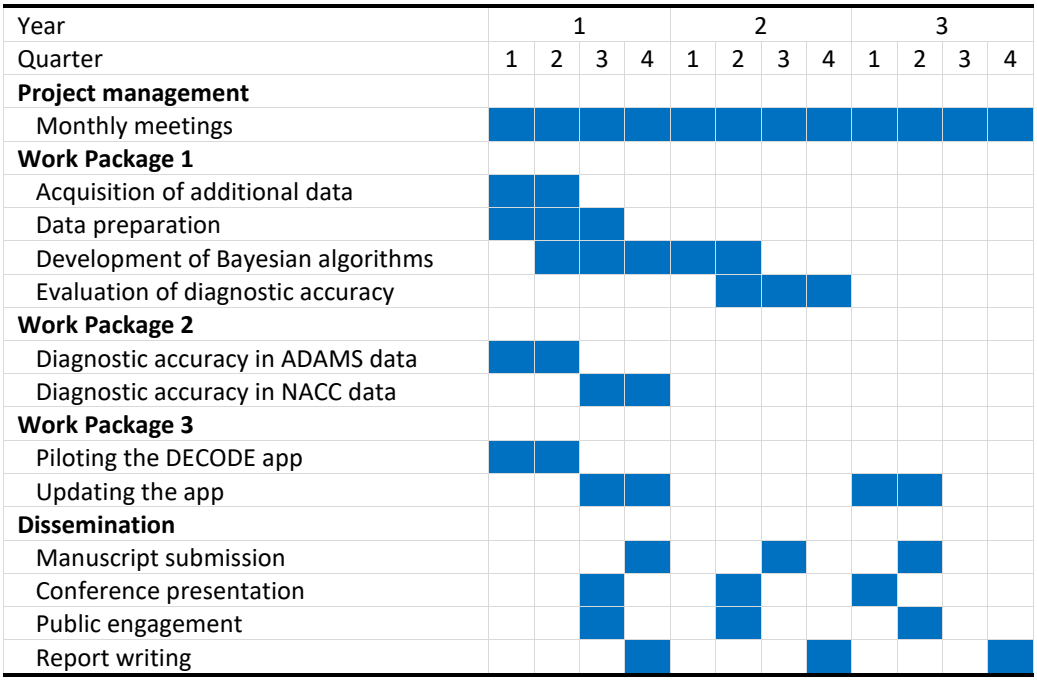
Budget

The majority of the support requested is for Janice Ranson to undertake her PhD with us (Work Package 1; CV appended) and postdoctoral researcher Dr Ela Kuzma to work on the project in year 1 (Work Packages 2 and 3; CV also appended).

Funding requested from the Halpin Charitable Trust	
Postdoctoral researcher (Year 1, ~76% FTE)	£35,100
Contribution towards PhD stipend	£36,900
Postgraduate fees	£13,100
App development in year 3	£5,000
Conference travel and dissemination	£5,000
Computer	£800
General consumables and incidental expenses	£1,000
Meetings with patients and clinicians	£3,100
Subtotal	***£100,000***
Match funding secured from the University of Exeter	
App development in year 1	£15,000
Contribution towards PhD stipend	£15,000
Subtotal	***£30,000***
Total	***£130,000***

(Note: all budget items costed to nearest £100)

Project timeline



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3. Department of Health (2013). *The Prime Minister's challenge on dementia: Delivering major improvements in dementia care and research by 2015: Annual report of progress.*
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19. Erdreich, L.S., & Lee, E.T. (1981). Use of relative operating characteristic analysis in epidemiology - a method for dealing with subjective judgment. *American Journal of Epidemiology, 114*, 649-62.

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Option 2

Refining and validating algorithms to identify dementia

The second option is more modest in scope, though would still allow us to refine our predictive models and provide Janice Ranson with a PhD studentship to join our group.

Overarching aim: To refine and validate our algorithms which combine clinical characteristics to identify dementia more accurately

Potential impact

The current version of our algorithms are based on only one study (ADAMS) and as such are not likely to generalize to other contexts and populations. By adopting a more sophisticated Bayesian approach to model development, and by incorporating data from several different well designed studies, we will ensure that our models are robust and clinically relevant (see Work Package 1 of Option 1 for a full description). We would still need to apply for further funding to enable us to evaluate the diagnostic accuracy of the brief cognitive assessments available (Work Package 2) and to refine our computerized decision support system (Work Package 3), though this would nevertheless allow us to make considerable progress.

Budget

The majority of the support requested is for Janice Ranson to join our group and undertake her PhD with us in years 1-3.

Funding sought from the Halpin Charitable Trust	
Contribution towards PhD stipend	£36,900
Postgraduate fees	£13,100
Subtotal	**£50,000**
Match funding secured from the University of Exeter	
Contribution towards PhD stipend	£15,000
Subtotal	**£15,000**
Total	***£65,000***

(Note: all budget items costed to nearest £100)

Option 3

Refining our computerized decision support system to detect dementia

The last option is the most limited in scope, and would allow us to refine our smartphone app only.

Overarching aim: To refine our smartphone-based computerized decision support system

Potential impact

By funding the refinement of the DECODE app we will be able to improve its content and usability (see Work Package 3 of Option 1 for a full description). We would still need to apply for further funding to enable us to fully develop the underlying algorithms (Work Package 1) and evaluate the diagnostic accuracy of the brief cognitive assessments available (Work Package 2), though this options would help us to make some progress in the meantime. This is our least preferred option as it would not provide sufficient funding for Janice Ranson to join the team and undertake her PhD with us.

Budget

The majority of the support requested is for postdoctoral researcher Dr Ela Kuzma to work part-time on the project in year 1.

Funding sought from the Halpin Charitable Trust	
Postdoctoral researcher (Year 1, 37% FTE)	£16,900
Meetings with patients and clinicians	£3,100
Subtotal	***£20,000***
Match funding secured from the University of Exeter	
App development	£15,000
Subtotal	***£15,000***
Total	***£35,000***

(Note: all budget items costed to nearest £100)

Janice M. Ranson, BSc, MSc, MBPsS
University of Exeter Medical School
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Email: j.ranson@exeter.ac.uk

PERSONAL STATEMENT

I am an early career researcher at the University of Exeter Medical School, with a strong track record for academic success and several years of experience in research, clinical and community-based work. My research interest is in the field of dementia and I am particularly passionate about evidence-based healthcare improvements and usability in clinical product development. During my undergraduate degree in Psychology I gained practical experience in conducting neuroscience and psychological research, and completed two theses in my final year; a comparative neuroanatomy study and a literature review assessing usability in assistive technology development. My master's dissertation provides the proof-of-principle for DECODE, for which I developed and validated a paper-based version of our clinical tool. In addition to academic research, I have a background of working within safeguarding, occupational health, mental health and community-based settings including support work, conducting interviews and standardised assessments.

For the past two years I have been working closely with Dr Llewellyn and Dr Kuzma, developing the concept and underlying evidence for DECODE. Following a very successful year-long research apprenticeship, I have continued to gain valuable experience by working on the project part time in an honorary capacity, pending PhD studentship funding which would allow me to complete the next phase of the project as a doctoral student. To date I have received three awards in relation to this work and have presented our results at the Alzheimer's Association International Conference 2015.

APPOINTMENTS

2015 – Present	**University of York**, Incredible Years E-SEE trial Data Collector
2014 – Present	**University of Exeter Medical School**, Mental Health Research Group Honorary Associate Research Fellow in Clinical Epidemiology
2014 – Present	**Devon and Cornwall Police**, Intelligence Directorate Operational Intelligence Researcher for serious crime and safeguarding
2012 – 2013	**Fremantle Media**, Accounting and Legal Department Finance Assistant
2011 – 2012	**South West London and St George's NHS Mental Health Trust** Activity Worker
2010 – 2012	**Home Start** Family Visitor
2010	**MIND** Research Assistant

EDUCATION

2013 – 2014	**MSc in Psychological Research Methods** (Distinction), University of Exeter Thesis: Development and Validation of a Dementia Screening Tool for use in Primary Care
2009 – 2012	**BSc in Psychology** (First Class Honors), Royal Holloway University of London Neuroscience Thesis: Evolution of the Primate Posterior Parietal Cortex Usability Thesis: User Involvement in Assistive Technology
2005 – 2007	**A Levels in Psychology, Sociology and Law** (Grades: A, A, B)

PRIZES AND HONOURS

2015	Alzheimer's Association International Travel Fellowship to the Alzheimer's Association International Conference 2015, Washington, D.C. (USA).
2015	MSc Psychological Research Methods Programme Prize for the best performance in my cohort.
2014	Dean's Commendation from the University of Exeter, in recognition of outstanding achievement.

PROFESSIONAL TRAINING

2015	Good Clinical Practice Training – NHS National Institute for Health Research
2015	Child Protection & Safeguarding – Devon Safeguarding Children Board
2015	Intermediate and advanced level Microsoft Excel for Windows – Devon and Cornwall Police Force
2014	Conducting Cognitive Assessments – Centre for Clinical Neuropsychology Research Group
2013	Introduction to STATA – Exeter Medical School
2013	MatLab and E-Prime behavioural experiment software – University of Exeter
2011	MRI brain imaging data analysis using FSL for Linux –Royal Holloway University of London

TALKS AND PRESENTATIONS

2015	*Primary Care Relevant Predictors of Dementia in the Aging, Demographics and Memory Study.* Poster session presented at AAIC, Washington DC.
2014	*Optimizing Brief Cognitive Assessments.* Peninsular Dementia Research Network Meeting, Exeter.
2014	*Recent Advances in Understanding Dementia.* Mental Health Research Group Seminar, Exeter.
2014	*Understanding Your Brain.* National Brain Awareness Week Lecture, Exeter.

Dr Elżbieta Kuźma
University of Exeter Medical School
College House, St Luke's Campus, Exeter (UK) EX1 4SG
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Email: e.kuzma@exeter.ac.uk

PERSONAL STATEMENT

I am a Research Fellow in Neuroepidemiology at the University of Exeter Medical School. I have a strong background in neuropsychology with particular expertise in the assessment of dementia and quantitative modelling. I completed my Diploma degree (equivalent to BSc and MSc) and my PhD in psychology at the University of Heidelberg, Germany. In my doctoral dissertation, I examined personality and person-environment interchange processes in mild cognitive impairment (MCI) and my diploma thesis focused on autobiographical memory in MCI; both of these research projects centered on analyses of longitudinal cohort data. Although my career is research focused, I also have relevant clinical experience. I performed and evaluated neuropsychological assessments and conducted cognitive training for patients with MCI in a Memory Clinic (Heidelberg University Hospital).

My research focuses on identification of potentially modifiable risk factors for Alzheimer's disease and dementia from a lifespan perspective and developing new tools to improve identification of dementia in primary care. I am particularly interested in improving our understanding of the roles of macrovascular and microvascular pathologies and vascular interventions in predicting dementia outcomes and modelling dementia probability using a Bayesian approach. Currently I am working on vascular aspects of cognitive impairment and dementia in a range of population-based studies including the US Health and Retirement Study (HRS) and the Cardiovascular Health Study (CHS).

APPOINTMENTS

2012 – Present	**University of Exeter Medical School** (UK), Mental Health Research Group Research Fellow (2013 – Present); Associate Research Fellow (2012 – 2013)
2007 – 2011	**Heidelberg University Hospital** (Germany), Section of Geriatric Psychiatry & Memory Clinic Research Assistant (2009 – 2011); Student Assistant (2007 – 2009); Intern (2007)
2005 – 2007	**University of Heidelberg** (Germany), Student Advisory Service Student Assistant
2006	**Coordination Centre for Clinical Studies Heidelberg** (Germany) Student Assistant
2006	**Max Planck Institute for Human Cognitive and Brain Sciences**, Leipzig (Germany) Intern

EDUCATION

2009 – 2012	**PhD in Psychology** (*magna cum laude*)**,** University of Heidelberg (Germany) Thesis: Personality and person-environment interchange processes in mild cognitive impairment Postgraduate Program: Cognitive Impairment in Old Age and the Spatial Everyday Environment, University of Heidelberg
2003 – 2009	**Diploma in Psychology** (equiv. to First Class Honors in BSc and MSc), University of Heidelberg (Germany) Thesis: Autobiographical memory in mild cognitive impairment

PRIZES AND HONOURS

2015	Alzheimer's Association International Travel Fellowship to the Alzheimer's Association International Conference 2015, Boston (USA)
2013	Alzheimer's Association International Travel Fellowship to the Alzheimer's Association International Conference 2013, Boston (USA)
2009 – 2012	Full PhD Fellowship from the State of Baden-Württemberg (Germany)
2007	Erasmus Scholarship, Universidad Autonóma de Madrid (Spain)

RESEARCH SUPERVISION AND TEACHING EXPERIENCE

2015 – 2018	**PhD dissertation co-supervisor**: Advanced modelling for the differential diagnosis of Alzheimer's disease, vascular dementia and other dementia subtypes
2013 – 2014	**MSc dissertation supervisor**: Coronary artery bypass graft surgery, dementia and cognitive decline: A systematic review and meta-analysis
2013	Academic Mentor in the Grand Challenges program for first year students, University of Exeter (UK)
2010 – 2011	Old Age Neuropsychology, postgraduate seminar leader, University of Heidelberg (Germany)

RESEARCH GRANTS

2015 – 2016	*The emerging relationship between vitamin D and dementia: is deficiency associated with memory decline?* Source: James Tudor Foundation; Role: Co-Principal Investigator; Amount: £25,000
2015 – 2016	*Opportunities and challenges in cognitive ageing: New interdisciplinary perspectives* Source: Klaus-Georg and Sigrid Hengstberger Award for Young Scientists; Role: Co-Principal Investigator; Amount: €12,500
2015 – 2016	*ARUK Scientific Conference Grant* Source: Alzheimer's Research UK; Role: Principal Investigator; Amount: £2,000

SELECTED PUBLICATIONS

Lourida, I., Thompson-Coon, J., Dickens, C.M., Soni, M., **Kuzma, E.**, Kos, K., Llewellyn, D.J. (2015). Parathyroid hormone, cognitive function and dementia: A systematic review. *PLoS One*. [Epub ahead of print]. doi:10.1371/journal.pone.012757

Wettstein, M., **Kuzma, E.**, Wahl, H.-W., Heyl, V. (2015). Cross-sectional and longitudinal relationship between neuroticism and cognitive ability in advanced old age: The moderating role of severe sensory impairment. *Aging & Mental Health*. [Epub ahead of print]. doi:10.1080/13607863.2015.1049119

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Kuzma, E., Sattler, C., Toro, P., Schönknecht, P. Schröder, J. (2011). Premorbid personality traits and their course in mild cognitive impairment: Results from a prospective population-based study in Germany. *Dementia and Geriatric Cognitive Disorders, 32,* 171-177.