NIHR HTA Programme

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The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton, manages evaluation research programmes and activities for the NIHR

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CAREDEM Trial
A pragmatic randomised controlled trial to evaluate the effectiveness and cost effectiveness of Collaborative cARE for people with DEMentia in primary care

CAREDEM ~ WORK PACKAGE 2

The effectiveness of collaborative care for people with memory problems in primary care: CAREDEM study

Protocol ID: NCTU: 11/0405

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HTA, University College London, Kings College London, the London School of Economics, the charity For Dementia and the Universities of Kent, Manchester and Newcastle

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2. Protocol Signature Page

2.1 Protocol Authorisation Signatories

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Signature..... Date.....
Dr Nick Steen, Statistician

Signature..... Date.....
Dr Vanessa Hogan, Trial Manager

4. GLOSSARY OF ABBREVIATIONS

BPSD	Behavioural and Psychological Symptoms of Dementia
CCI	Collaborative Care Intervention
CI	Chief Investigator
CPNs	Community Psychiatric Nurses
DMEC	Data Monitoring and Ethics Committee
GPs	General Practitioners
GPSIs	General Practitioners with Special Interest
NDS	National Dementia Strategy's
PCT	Primary Care Trust
PPI	Patient and Public Involvement
QRD	Alzheimer's Quality Research and Development group
REC	Research Ethics Committee
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom
US	United States

5. KEYWORDS

Collaborative Care, Care Manager, Case Manager, Care Pathways, Dementia, Intervention Development, Primary Care, Qualitative Methods,

6. Responsibilities

	Responsibility to:	Responsible Party	If responsibility is delegated, name body / individual that it is delegated to:
1. Study preparation	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor	
	b) Secure and administer funding for the Study.	Sponsor	Chief Investigator
	c) Secure and contract for the supply of resources including medicinal products/devices/CRO services.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor	
2. Applications and Registration	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor	
	b) Prepare Participant information sheet and consent form, including where appropriate consent to providing Participant tissue, sample, medical data or other material to the Sponsor and other relevant documents prior to ethics submission.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	c) Prepare and submit ethics application.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Register the Study with an appropriate protocol registration scheme.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Obtain NHS permission.	Sponsor	
3. Protocol Amendments	a) Prepare and submit proposed substantial amendments of the Protocol to the regulatory authority(ies), relevant ethics committee and NHS Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

	b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
4. Study Conduct	a) Ensure that legislation in relation to research is followed	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	b) Ensure that the study team members are appropriately qualified and experienced to undertake the conduct of the Study and that they have current substantive or honorary employment contracts in place, where required.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	c) Ensure that no Participant is recruited until a favourable ethical opinion has been provided	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	d) Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	e) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and Clause 2 of this Agreement	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	f) Ensure that the Study is managed, monitored and reported as agreed in the Protocol.	Sponsor	Chief Investigator / Newcastle Clinical Trials
	g) Ensure that the rights of individual Participants are protected whilst participating in the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	h) Maintain and archive Study documentation.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.

	i) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit.
	j) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	k) Report suspected research misconduct.	Sponsor	Chief Investigator
	l) Notify the regulatory authority(ies) of the end of the Study.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	m) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
5. Data Management	a) Design of questionnaires and database.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
	b) Ensure appropriate analysis of data.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
6. Publication	a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit
7. Archiving	a) Ensure that all Study records are archived appropriately on conclusion of the Study and retained for seven (7) years	Sponsor	Chief Investigator / Newcastle Clinical Trials Unit

7. Protocol Summary

Full title:	CAREDEM Work package 2 The Effectiveness of Collaborative Care for People with Memory Problems in Primary Care.
Short title:	The Effectiveness of Collaborative Care Feasibility Study
Protocol version:	2.0
Protocol date:	04/01/2012
Chief Investigator:	Professor Steve Iliffe
Sponsor:	University College London
Funder:	NIHR HTA (08/53/99)
Study design:	This is a non-commercial Intervention Development study (Work package 1) to adapt and customise the care pathways used in the PREVENT study[7] into a Collaborative Care Intervention for use in the planned CAREDEM Pilot Rehearsal Study (Work package 2), and potential follow on Main study (Work package 3), with a nested Qualitative study (Work package 4) in each work package.
Feasibility Study objectives:	To ensure the case management skills and the collaborative care model will be easy to acquire and apply.
Study sites:	Newcastle, London, Norfolk.
Study population:	Patients of any age with a diagnosis of any type of dementia (confirmed by secondary care assessment) who are living independently in the community and who have a main informal carer (spouse, close relative or other informal care giver) who maintains regular contact
Study duration:	18 months

8. The CAREDEM study ~ An overview

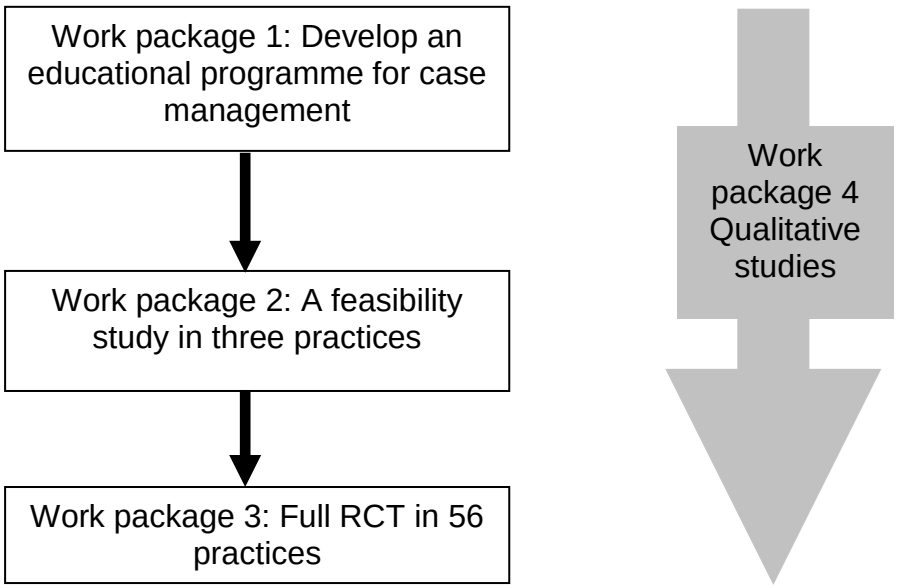
The CAREDEM trial will test the potential of case management for people with dementia to improve the quality of life and outcomes of people with dementia and their carers.

In case management an experienced professional (practice or district nurse, community psychiatric nurse or social worker) will use methods developed for the trial to help people with dementia and their families deal with the challenges of a progressive disease process.

Case management methods need to be specific to the disease. This study will take methods pioneered in the USA and adapt them to the NHS, using the expertise of professionals and service users to do so.

This protocol describes the second work package (work package 2) of a randomised controlled trial, in which the previously developed educational programme (work package 1) will be tested in a small feasibility trial. If the trial demonstrates that the educational programme fits into everyday practice and also shows positive benefits it will then be evaluated in a large scale randomised controlled trial (work package 3).

The experiences of patients, carers and professionals involved in the study will be sought in all work packages using qualitative interviews, and these constitute a fourth work package, running in parallel with the first three. The flow of the overall study is shown below.



9. Background

Our ageing population and implications for NHS care: Life expectancy is increasing by two years per decade. Older people represent the fastest growing sector of our population. In the United Kingdom (UK), improving the health and social care of our ageing population is one of the key priority areas for health care policy [1] [2]. Our ageing population will lead to an increase in age-related illnesses, such as dementia, and will present considerable challenges for healthcare providers in the future. This will be particularly so for primary and community services following the recommendations of the latest White Paper, *Our heath, our care, our say,* which stipulates that care for older people, and for those with long term conditions, should be delivered as close to their homes as possible [3].

Dementia - current impact and burden: Dementia is one of the main causes of disability in later life; in terms of Global Burden of Disease, it contributes 11.2% of all years lived with disability, higher than stroke (9.5%), musculoskeletal disorders (8.9%), heart disease (5%) and cancer (2.4%). One in 14 people aged over 65 has a form of dementia, rising to one in six of those over 85. In the UK, there are currently around 700,000 people with dementia but this is estimated to rise to 1 million by 2020 and 1.7 million by 2050, an increase of over 150% [4]. The total costs of caring for people with dementia in the UK have been estimated at between £17 and £18 billion a year [4], more than heart disease (£4 billion), stroke (£3 billion) and cancer (£2 billion). Currently around two thirds of people with dementia live in private households, with the majority of their care provided by family supporters and primary and community care teams [4]. However the steady fall in the number of long-term care places available for people with dementia, together with the rising numbers of older people generally, will lead to an increasing number of frail older people requiring complex care packages if they are to continue to live independently and hence postpone or avoid moving into institutional care.

Dementia care in the UK - existing provision and evidence: There is evidence that the standard of dementia care in the UK is in urgent need of improvement, with frequent failure to deliver services in a timely, integrated or cost effective manner to support people with dementia and their families to live independently for as long as possible [10]. Within primary care, general practitioners admit to difficulties both in dementia diagnosis and common areas of dementia management [10]. In the UK, dementia detection rates have been increased through the use of educational interventions in primary care but in terms of dementia care, alternative models of service delivery have not been explored. Research from outside the UK has revealed the potential of a collaborative care model for both the assessment [11] and care of people with dementia [7 12]**,** with demonstrated benefits in quality of life and other measures.

Case management and collaborative care: In mental health, case management is a particular type of collaborative care [13], in which workers known as 'case managers' systematically follow up patients under regular supervision and (usually) provide both brief psychological therapy and medication management. Although the term case

manager is used in health care, care manager is used within social care. The origins of collaborative care lay in concerns about the inadequacy of much current treatment for depression and developments in the field of chronic physical disorders. 'Collaborative care' has itself been variously defined to mean everything from collaboration between services, and 'shared care' to the more highly structured definition that is now becoming accepted internationally [14].

The components of a collaborative care model for depression are: A) ***multi-professional approach to patient care*** provided by a case manager working with the GP under supervision from specialist mental health medical and psychological therapies clinicians; B) ***a structured management plan*** of medication support and brief psychological therapy; C) ***scheduled patient follow-ups*** ; D) ***enhanced inter-professional communication*** patient-specific written feedback to GPs via electronic records and personal contact.

In earlier studies of depression, mental health professionals provided the enhanced staff input to primary care settings and undertook a care co-ordinator role [15, 16]. More recently, primary care nurses [17, 18] were used to fulfil the role of care co-ordinator. Most studies of collaborative care have been from the US. In the UK, one published study using practice nurses in the care co-ordinator role did not improve either patient antidepressant uptake or outcomes compared with usual GP care [18], but Chew-Graham et al [19] demonstrated an improvement in depression outcomes utilising the collaborative care approach and flexible psychological intervention delivered by a mental health nurse. Christensen et al [20] in their systematic review of models of care for depression, suggested that components which were found to significantly predict improvement were the revision of professional roles, the provision of a case manager who provided direct feedback and delivered a psychological therapy, and an intervention that incorporated patient preferences into care.

Case management in dementia: Current national guidance on dementia care recommends the provision of coordinated health and social care, led by a single health or social care professional (care manager in social services but case manager in health care)[5]. This was also a key recommendation of recent reports on dementia care [10 21] and mirrors the views of people with dementia and their family carers . A United States (US) based trial (PREVENT) of such a collaborative care model, led by a nurse practitioner integrated in primary care [7], demonstrated significant improvements for both people with dementia (increased prescribing of cholinesterase and antidepressant drugs, fewer behavioural and psychological symptoms) and for their family carers (improved depression scores, higher carer satisfaction ratings). Our proposed intervention for dementia is derived from this US model [7]; however in the US trial, cost effectiveness of the intervention compared to usual care was not formally assessed and effects on institutionalisation could not be determined due to limited follow up, so we will address these questions. Challis and colleagues, [22], demonstrated the effectiveness of a model of intensive case management for people with dementia based in a community-based mental health

service for older people. Our proposed case manager role will be carried out by primary care practitioners working in liaison with secondary care services.

National Dementia Strategy and Care Advisers: The recently published National Dementia Strategy (NDS) has recommended the introduction of a new role, dementia care advisers as best practice for people with dementia[23]. The focus of the dementia care adviser will be to provide information to people with dementia and signpost them to additional sources of help and support. The strategy clearly states that this new role would not be that of intensive case management, as currently carried out by community mental health teams or Admiral Nurses, or as in the intervention we propose to evaluate in this trial. It is unclear (given their proposed relationship to the third sector) how much authority dementia advisers will have within health and social care. Equally unclear is how much they will be able to go beyond signposting people with dementias, by responding directly to complex situations, especially where co-morbidities interact with dementia. There are grounds for thinking that a simple advisory service will not meet all the needs of people with dementia, particularly when these needs are complex and related to the interplay of complex co-morbidities and pre-existing social relationships.

Summary: The number of people with dementia is predicted to rise by 150% over the next 40 years. There is consistent evidence that the standard of dementia care in the UK is in urgent need of improvement, with frequent failure to deliver services in a timely, integrated or cost effective manner to support people with dementia and their families to live independently for as long as possible. Current best practice guidance on dementia care recommends the provision of coordinated health and social care, led by a single health or social care professional (case manager)[5]. Such a collaborative care approach has shown promising benefits elsewhere; however there is a lack of UK-based research exploring the clinical and cost effectiveness of alternative models of service delivery in dementia care.

This study (work package 2) will firstly test the developed collaborative care Intervention and customised care pathway from work package 1 and will compare the impact of this collaborative care model in dementia against usual care in terms of both clinical and cost effectiveness.

10. Study Objectives

Primary Objective

To ensure the case management skills and the collaborative care model will be feasible to implement and apply in practice.

Secondary Objectives

The secondary objectives are to determine whether practices can recruit 11 patients into the study and that 9 patients can be contacted at 6 months.

11. Study Design

11.1 Background Information ~ Planned full CAREDEM trial

This current protocol focuses on the CAREDEM pilot rehearsal trial (Work package 2). In order to set this into context, details of the planned full CAREDEM trial are detailed below. Separate protocols and Ethics applications will be made for the planned CAREDEM Main Trial.

It is planned that the CAREDEM pilot and main trials will take place in general practice-based primary care in 3 centres; London and Norfolk in the South East of England and Newcastle in the North East of England. The aim will be to engage whole Practice Based Commissioning localities and consortia, in order to limit the geographical areas across which case managers will work, but with a target equivalent to 54 medium-sized general practices (with average list sizes around 6000). It is anticipated that each such practice will contribute 11 patients recruited to the main trial (WP3), 6 retained to 18-month follow-up; these rates of recruitment and retention will be reviewed and if necessary revised based on data from the pilot study (WP2).

The target patient population is people, of any age, with a diagnosis of any type of dementia (confirmed by secondary care assessment) who are living independently in the community and who have a main informal carer (spouse, close relative or other informal care giver) who maintains regular contact.

Those undertaking the case management role may be already in post within a community-based organisation (either individual general practice based primary care team, Primary Care Trust (PCT), Community Mental Health Team (CMHT), or social worker) depending on existing local arrangements, interest and expertise. We anticipate that most of those interested in taking on the case manager role will be nurses of the level of experience found at band 7, working in district nursing, as CPNs or possibly as practice nurses. They will receive additional training (to be developed in work package 1 and tested in work package 2), provided through the Admiral Nurse training organisation 'Dementia UK', with an induction period, periodic refresher days, experiential learning, mentoring and formal on-site supervision, via Admiral Nurses at the three planned study centres. Training will be delivered by a regional senior clinician from the project team and an Admiral Nurse, with other clinicians or allied medical professionals delivering specific training as required. In the PREVENT model training is over 8x2 hour sessions and it is anticipated that at least this amount of time will be necessary.

The full CAREDEM project consists of four work packages:

- Work package 1: Developing the intervention and customising care pathways from the PREVENT study
- Work package 2: Pilot (rehearsal) trial – the current protocol and study
- Work package 3: Main trial
- Work package 4: Qualitative study, extending across all three work packages.

The aim of the full CAREDEM trial is to embed a collaborative care approach, based on case management methods and evidence based care pathways, in primary care to enable better management of common problems in dementia. A multi-professional care co-ordination approach to patient care will be provided by a case manager working with the patient's GP and liaising with specialist mental health services, social services and third sector organisations as necessary. The practitioners with case manager roles will be located within primary care to coordinate care and liaise regularly with GPs, and will be supervised by Admiral Nurses. Training in collaborative care and case management techniques will be offered to district nurses, practice nurses, social workers, General Practitioners with Special Interest (GPSIs) or other existing primary care practitioners as determined by the local skill mix and local commissioning needs and intentions. Scheduled patient follow-ups will be included as part of the case management process, with the frequency and location of meetings being client-led. Enhanced inter-professional communication and liaison using patient-specific written feedback to GPs via electronic records as well as personal (face to face or telephone) contact will be an integral part of the case management method.

11.2 Work package 2 ~ Pilot rehearsal trial

This work package will consist of a rehearsal trial plus engagement of PCTs, Practice Based Commissioning localities and consortia, individual practices and other relevant services and agencies in preparation for the main trial.

Prior to the full trial, we will conduct an 18 month rehearsal pilot study in three practices, one in the northern region and one each in London and Norfolk to check assumptions about practice and patient recruitment and retention, confirm the acceptability of brief intervention procedures and to ensure the feasibility (data yield and quality) of proposed outcome measures and, if necessary, adjust our sample size calculation. Practices which take part in the rehearsal study will not participate in the main trial. Practices will be asked to actively recruit patients over a three month period. Study outcomes will be collected at 6 months post intervention.

The objective for the pilot phase is to ensure that case management skills and the collaborative care model will be easy to acquire and apply and that they will become a form of 'soft technology' that will be incorporated into routine practice. The key success criteria for the pilot trial are if practices can recruit 11 patients into the study (depending on practice size), that 9 can be contacted at 6 months and that stakeholders find the intervention procedures acceptable and feasible within routine NHS practice. We will then extrapolate rates of retention to 18 months based on retention at 6 months in this pilot and trends thereafter in comparable studies. There will also be a nested qualitative study within this rehearsal study.

Eligible patients and carers will be identified from the practice dementia register by a member of practice staff and contacted by their GP. If they give verbal consent to being contacted directly by the research team, this will be documented by the GP and their contact details forwarded to the research team. If patients or carers wish to receive further information before making a decision, the GP will send the patient an information sheet, an opt in form and a pre paid envelope. Once the expression of interest form or verbal consent form has been received, the research team will then contact them and answer any questions and arrange a visit at the participant's

workplace or home or other place specified by them to obtain informed consent. During this visit they will also be asked about their experience of the process of recruitment and giving consent and their expectations of the case management approach. Given that patients will have cognitive impairment, it is essential to collect this data at the time, since patients may have difficulty in retrospectively commenting on their experience and expectations at a later date. Once patients and carers have given informed consent, baseline data will be collected by the research team member prior to the case manager delivering the intervention developed in work package 1. Follow up data will be collected at 6 months.

In order to describe and develop an understanding of the various mechanisms at work and allow a look at some of the outcomes of the intervention, an exploration of user and provider perspectives will be undertaken. We will employ in-depth interviews and focus groups in order to meet the objectives. In total, up to 20 individual interviews will be carried out with people with dementia (and their carers where appropriate) and case managers delivering the intervention across the three pilot practices in two different geographical sites (Newcastle in the North of England and London and Norfolk in the South of England). Three focus groups, one from each practice , will be carried out bringing together the organisational framework in which this intervention is embedded (participants will be drawn from GPs, nurse managers, commissioners from social and health services) in each pilot site.

11.3 Work package 4 – (Qualitative Sub Study)

Purpose

The risk with all technology developments is that the new product will not work outside the designer group, and this qualitative component (Work package 4) is an attempt to avert that. It is necessary to be able to identify (prospectively in the planned CAREDEM pilot rehearsal study (Work package 2), and potential follow up on main study (Work package 3) the ‘active ingredient’ of the intervention if the planned trial shows benefit. The qualitative component will help elucidate what goes on in the intervention development process and so help with later implementation processes. Capturing this information will also allow for the detection of previously unrecognised design faults (again, prospectively in Work packages 2 and 3) should the planned trial show that the intervention is not effective.

The purpose of the nested qualitative work package 4 (WP4) within this pilot feasibility study work package (WP2) is therefore to evaluate the acceptability of the intervention from three perspectives: the user (person with dementia and their informal carer where appropriate); practitioner (case manager, health and social care practitioners) and the organisation (providers and commissioners of old age and mental health services and social care). Methods of data collection employed to meet the above objectives include individual interviews and focus groups. To understand the implementation of the intervention we will observe and/or audio record the training and supervision provided for case managers as well as a sample of routine case management meetings (for which permission will be sought from people with dementia and carers).

11.4 Patient and Public Involvement

The CAREDEM proposal arose from discussions within the DeNDRoN Primary Care and Dementia Clinical Study groups, both of which have PPI representatives who have contributed to the discussion about the intervention and desirable outcomes. The PPI group that guides For Dementia will contribute members who will participate in the management of the entire CAREDEM study (work packages 1-4) at all levels, and the For Dementia Chief Executive will be responsible for liaison with this group. The Co-Director of the Social Care Work Force Unit will be responsible for PPI involvement in the management of the trial, at trial steering committee, trial management and site management committee levels, and also in the PPI forum. A PPI forum will be established to allow individuals who do not wish to join the management committees to participate in debates about the development of the case management training, the content of the care pathways, the optimal ways to engage people with dementia and their carers in the trial, the interpretation of findings and the planning of dissemination. The invitation to join this forum will be extended to Alzheimer's Society Research and Development group (QRD), the For Dementia Carer' group, the Greater London Forum for Older People and other relevant bodies.

An Information Sheet with details of work package 2, the feasibilty study, will be provided to potential members of work package 2.

11.5 Outcome measures

Primary Outcome Measures

The primary outcome measure (on which the sample size calculations are based) for the trial will be the Neuropsychiatric Inventory (NPI) measured at 6 months. This is a validated instrument with 12 domains, completed by carer interview to assess the prevalence of BPSD in people with dementia. Cost effectiveness of the intervention will be the other primary outcome, assessed from a societal perspective, based on comprehensively measured costs and outcomes measured using the NPI.

For the qualitative study the primary outcome will be an understanding of the feasibility and acceptability of the intervention and participation in the research study.

Secondary Outcome Measures

To be assessed at baseline and 6 months post-randomisation for the person with dementia and their carer will include:

Patient

Cognitive function via the Mini Mental State Examination (MMSE). Functional impairment as assessed by the Bristol Activities of Daily Living Scale and Institutional rates and Quality of Life via the Qol-AD, a validated disease specific measure for dementia and DEMQOL, a generic measure from which it is possible to generate QALYs (quality of life adjusted health years (Smith et al 2007); Societal weights will be applied.

Carer

Mood/depression via the GHQ-28, a 28 item questionnaire that gives a measure of a carer's general distress and strain and Quality of life (HSQ-12 and ii) EQ-5D, a

generic measure to generate QALYs (quality of life adjusted health years; societal weights will be applied.

Service use
The Client Service Receipt Inventory (CSRI) captures service utilisation data for the carer and the patient (including institutionalisation, extra patient care during therapy), unpaid carer support and other aspects relevant to health economics. Rates and dates of entry into institutional care will be recorded.

Adverse events
Number of patient deaths and other adverse events such as emergency admission to hospital

12. Data handling, record keeping and confidentiality

Data collection and transfer in this trial will comply with NRES and Caldicott guidelines and the Data Protection Act 1998. All study documentation will be held in secure offices, and the research team will operate to a written and signed code of confidentiality.

A clinical data management software package will be used for data entry and processing, allowing a full audit trail of any alterations made to the data post entry. Identifiable data will be kept for the duration of the trial and thereafter destroyed.

Long term storage: All study documentation will be archived and held for 10 years by the study sponsor.

13. Ethics and Regulatory Issues

13.1 Ethical Arrangements

The conduct of this study will be in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Prior to beginning work package 2, a favourable opinion will be sought from an appropriate Research Ethics Committee.

This study does not fall within the scope of ‘The Medicines for Human Use (Clinical Trials) Regulations 2004’ as it is not a study of investigational medicinal products.

Separate protocols will be prepared and an ethics application will subsequently be made for work package 3 with their respective nested qualitative components.

13.2 Indemnity

NHS Trusts have liability for clinical negligence that harms individuals toward whom they have a duty of care. NHS Indemnity covers NHS staff and medical academic staff with honorary contracts conducting the study for potential liability in respect of

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

13.3 Sponsor

University College London will act as sponsor for the whole study

13.4 Funding

The NIHR HTA is funding this study (funding reference 08/53/99)

13.5 Audits

The study will be open to audit by the research governance teams of sponsor and host organisations, either as part of their 10% routine audit, or 'for cause' by the sponsor or by other relevant regulatory bodies to ensure adherence to GCP and the NHS Research Governance for Health and Social Care (2nd Edition).

14. Study Management

The day to day management of work package 2 will be co-ordinated through the Newcastle Clinical Trials Unit.

15. Study Report/ Publication

The data will be the property of the Chief Investigator and Co-Investigator(s). Publication will be the responsibility of the Chief Investigator. It is planned to publish this study in peer review articles and to present data at national and international meetings. Results of the study will also be reported to the sponsor and the funder and will be available on their websites. The NIHR HTA will be acknowledged on each publication. All manuscripts, abstracts or other modes of presentation will be reviewed by the Trial Steering Committee and funder prior to submission. Individuals will not be identified from any study report.

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