The effectiveness of Collaborative Care feasibility study

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
24/05/2012		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
24/05/2012		[X] Results		
Last Edited 12/05/2016	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

Dementia is one of the main causes of disability in later life, causing more disability than stroke, arthritis and other joint diseases, heart disease and cancer. 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%. The standard of dementia care in the UK is very variable. The fragmentation of services for people with dementia and their families has been acknowledged by the National Dementia Strategy (NDS). The NDS proposes dementia care advisers, who will give information to people with dementia and their carers, and act as signposts to services and support. Our proposal is to test one interpretation of the proposed advisers' role. Research from the USA has revealed the potential of a 'collaborative care' approach. Collaborative care means professionals from different backgrounds (general practitioners, specialists in old age psychiatry, community mental health nurse) support a 'case manager' who works closely with the patient and their family. This close working relationship is based on a management plan of support, brief psychological therapy and where appropriate medication that is tailored to each person with dementia and their family or other carers. The plan will include well-thought out ways of managing communication issues; behaviour problems (agitation, aggression); mobility; personal care; sleep; legal and financial issues; physical health; depression and anxiety; psychotic symptoms; and carer support. The management plan includes regular, planned follow-ups and the case manger keeps all the relevant professionals informed about progress. We do not think that this case manager needs to be a new kind of professional. On the contrary, case management methods can be learned and applied by professionals already working in the community. District and practice nurses are already working with people with dementia, and could apply case management methods systematically if trained to do so. General practitioners with a special interest in dementia could also take on the case manager role. Our study proposes to test these ideas, and measure their effect on people with dementia and their carers.

Who can participate?

People with dementia who live independently in the community

What does the study involve?

In the first part of the study we adapt the US case management methods to the circumstances of the NHS, and develop a training programme that could be used throughout the health service

if the method proves effective. The second part of the study is a 'dress rehearsal' for a large scale study. The dress rehearsal is carried out in a small number of practices, to test that the training works, and that its effects can be measured. If there are problems with the training package, or difficulties in recruiting practice, they can be identified and rectified at this stage.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Newcastle University (UK)

When is the study starting and how long is it expected to run for? June 2012 to December 2012

Who is funding the study? Health Technology Assessment Programme (UK)

Who is the main contact? Dr Vanessa Hogan v.e.hogan@ncl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Vanessa Hogan

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 12134; HTA 08/53/99

Study information

Scientific Title

The effectiveness of Collaborative Care for people with dementia in primary care

Study objectives

The study will consist of a pilot rehearsal trial plus engagement of primary care trusts, Practice based commissioning localities and consortia, individual practices and other relevant agencies and services.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/085399
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/52967/PRO-08-53-99.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES West London and South East Coast Surrey Research Ethics Committees, 28/09/2011, ref: 11 /LO/1555

Study design

Non-randomised interventional trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Dementias and Neurodegenerative Diseases

Interventions

Pilot study, Our intervention is to pilot the previously developed Collaborative Care Intervention in primary care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

NPI questionnaire measured at 6 months post intervention.

Secondary outcome measures

MMSE, BADLS, Qol-AD and DEMQOL questionnaires measured at baseline and 6 months post intervention

Overall study start date

01/06/2012

Completion date

01/12/2012

Eligibility

Key inclusion criteria

- 1. People with a diagnosis of any type of dementia, confirmed by secondary care assessment.
- 2. Living independently in the community at the time of baseline assessment and with a spouse, close relative or other informal carer who maintains regular contact and who can be approached as a potential participant and informant
- 3. Target Gender: Male & Female

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 44; UK Sample Size: 44; Description: 44 patients in total. 11 patients per GP practice.

Key exclusion criteria

- 1. People with a diagnosis of dementia who are living in institutional care
- 2. People with a diagnosis of dementia deemed in need of pallative care (less than 12 months to live, as assessed by the patient's GP)

Date of first enrolment

01/06/2012

Date of final enrolment

01/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Newcastle University Newcastle Upon Tyne United Kingdom NE2 4HH

Sponsor information

Organisation

University College London (UK)

Sponsor details

Department of Primary Care and Population Sciences Hampstead Campus Rowland Hill Street London England United Kingdom NW3 2PF +44 (0)20 7679 2000 abc@email.com

Sponsor type

University/education

Website

http://www.ucl.ac.uk/

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No