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DIAMOND-Lewy: A pilot study of care provided by NHS services

Submission date
15/12/2016

Recruitment status
No longer recruiting

Registration date
20/01/2017

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dementia is a common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worse over time. Dementia with Lewy Bodies (LBD) and Parkinson's disease Dementia (PDD) together are known as Lewy Body Dementia (LBD). They share common clinical features and biology, and also respond to similar approaches to management. Currently there is evidence that LBD is often not recognised or managed properly, even in specialist hospital services. The signs and symptoms of LBD can be very hard to detect. Ensuring appropriate management of dementia is central to improving care for patients. At the moment there is no simple tool that includes the full range of LBD symptoms, and no real evidence based management care pathway. Currently there is not enough information to say if any one method used by doctors is better than the others for effective patient management. This study is looking at a newly developed management toolkit, which has been designed to help services to better manage LBD patients. The aim of this study is to compare usual management methods and the new management toolkit in order to evaluate the effect of the toolkit on patient symptoms, outcomes, quality of life and carer stress.

Who can participate?
Patients aged 60 years and over with LBS

What does the study involve?
Participating services are randomly allocated to one of two groups. Services in the first group continue to manage their patients in the usual way, which may vary from service to service. Services in the second group are provided with the management toolkit and encouraged to use this as and when appropriate with all of their patients. The management toolkit is a recommended guideline and can be used according to clinician judgment, either on a single visit or on multiple visits. In both groups, patients and carers attend hour and a half-long visits at the start of the study and then after three and six months. Each visit involves the patient completing a number of questionnaires with a qualified assessor. The carer/informant then seperately completes a number of questionnaires relating to both themselves and the patient.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved to those participating.

Where is the study run from?
21 NHS dementia services in East Anglia and the North East of England (UK)

When is the study starting and how long is it expected to run for?
September 2015 to February 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Sarah Dunn
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Contact information

Type(s)
Public

Contact name
Ms Sarah Dunn

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Additional identifiers

Protocol serial number
30476

Study information

Scientific Title
Improving the diagnosis and management of neurodegenerative dementia of Lewy body type in the NHS.
Work Package 5A and 5B: A pilot cluster randomised study of the management toolkit in the NHS secondary care services

Acronym
DIAMOND-Lewy

Study objectives
The aim of this study is to see if a newly developed management toolkit will result in symptom improvement, increased quality of life and decreased carer stress in patients with Lewy Body Dementia (LBD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Coventry and Warwickshire REC, 17/02/2016, ref: 16/WM/0025

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Process of Care, Management of Care

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Dementias and neurodegeneration, Primary sub-specialty: Dementia; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

Interventions
Services are randomised to receive either the management toolkit (interventional sites) or to continue their usual management of the patients (control sites). The management toolkit is a recommended guideline and will be used according to clinician judgment in the intervention arm. It could be used at a single visit only, or over multiple visits/patient contacts across several months. The management toolkit will be used as part of routine practice and will remain with sites after the end of the study. Additional study visits will be conducted at baseline, 3 months and 6 months, and clinicians in the intervention arm will be asked to complete a clinician toolkit use questionnaire.

The patient and carer will take part in 3 visits (baseline, 3 and 6 months) which will take place at their home over a 6 month period. Each visit will take approximately 1 hour 30 minutes. Each visit involves the patient completing a number of questionnaires with a qualified assessor. The carer/informant will separately complete a number of questionnaires relating to both themselves and the patient. If both the patient and carer can be present, 2 members of the team will conduct the visit when possible. The final study visit will be done at 6 months (+/- 2 weeks) after the baseline visit. This will be the end of the study for patients and carers/informants.

Intervention Type
Other

Primary outcome(s)
1. Feasibility of use of the intervention is assessed by Clinician Toolkit Feedback Questionnaire at approximately 6 months after service has been randomised and at the end of the trial.
2. Impact of the assessment and management toolkit on patient management, health outcomes, and its impact on informants/carers is assessed by this is assessed through collection of outcome measured at baseline, 3 and 6 months

3. Cost-effectiveness of the new assessment and management toolkit for LBD with usual care is assessed by this is assessed by the Use of services and costs Questionnaire at Baseline, 3 months and 6 months and Time and Travel Questionnaire at 6 months as listed below

Key secondary outcome(s)
1. Symptom severity is measured using the reduced Neuropsychiatric Inventory (NPI) score; lower unified Parkinson's disease rating scale (UPDS) score; Dementia Cognitive Fluctuation Scale (DCFS-R), lower Cornell depression score, Galvin Lewy Body Composite Score and Geriatric Depression Scale at baseline, 3 and 6 months
2. Patient quality of life is measured using the patient EQ-5D-5L and carer proxy EQ-5D-5L; patient DEMQOL and carer DEMQOL-proxy scales at baseline, 3 and 6 months
3. Rates of cognitive decline is measured using the MMSE and MoCA scales at baseline, 3 and 6 months
4. Carer stress and quality of life is measured using the carer EQ-5D-5L; HADS; and Zarit burden scale at baseline, 3 and 6 months
5. Global outcome is measured using the Global outcome Scale at 3 months and 6months.
6. Heath economic measures are measured using the non-standardised questionnaires developed by the research team as follows: Time and Travel Questionnaire at 6 months and Use of services and costs Questionnaire at Baseline, 3 months and 6 months

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. A clinician diagnosis of LBD has been documented as the result of specialist service assessment (possible or probable diagnosis)
2. Consent can be obtained from the patient or, for those subjects lacking capacity, from a consultee

In addition to the above criteria:
WP5A: Patients aged 60 and over with at least 1 active clinical issue as determined by the treating clinical team.
WP5B: Patients aged 60 and over with a diagnosis of Parkinson's disease where a memory problem has developed.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment

Key exclusion criteria
1. Patients who have explicitly expressed a wish not to be approached to take part in research
2. Patients who have been approached to take part in this study previously (as part of another participating service)
3. Patients who have a severe or terminal illness and reduced life expectancy which compromises their ability to comply with the protocol
4. Insufficient English to allow completion of the study measures
5. Patients who are assessed as not able to complete the outcome measures for the study. Clinicians may choose not to use the management tool at some assessments if they feel it is not appropriate.

Date of first enrolment
22/04/2016

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newtown Centre
Nursery Road
Huntingdon
United Kingdom
PE29 3RJ

Study participating centre
Peterborough Memory Clinic
Dementia Resource Centre
441 Lincoln Road
Millfield
Peterborough
United Kingdom
PE1 2PE

Study participating centre
Specialist Dementia and Frailty Service
Western House

Chapel Hill
Stansted
United Kingdom
CM24 8AG

Study participating centre
Cambridge Memory Clinic
Deighton Centre
Ida Darwin
Cambridge Road
Fulbourn
United Kingdom
CB21 5EE

Study participating centre
Julian Hospital
Bowthorpe Road
Norwich
United Kingdom
NR23 TD

Study participating centre
Chatterton House
Goodwins Road
King's Lynn
United Kingdom
PE30 5PD

Study participating centre
Gateway House
Farrier Close
Wymondham
United Kingdom
NR18 0WF

Study participating centre
Wedgewood House
West Suffolk Hospital
Hardwicke Lane

Bury St Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Elderly Medicine Movement Disorder Clinic
Norfolk & Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury St Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Tracey Ward Disability resource Centre
Unit 4
Bunting Road
Bury St Edmunds
United Kingdom
IP32 7BX

Study participating centre
The Priory Memory Clinic
Hawkeys Lane
North Shields
United Kingdom
NE29 0SF

Study participating centre
Jubilee Day Hospital
Parkinson’s Service
North Tyneside General Hospital
North Shields
United Kingdom
NE29 8NH

Study participating centre
North Tyneside Hospital
MHSOP
North Shields
United Kingdom
NE29 8NH

Study participating centre
Northumberland Community Services
Older Persons Service
Community Care Group
Hexham General Hospital
Hexham
United Kingdom
NE36 1QJ

Study participating centre
Older People's Mental Health Services
West Wing
St George's Park
Morpeth
United Kingdom
NE61 2NU

Study participating centre
Monkwearmouth Hospital
Memory Protection Service
1st Floor
Newcastle Road
Sunderland
United Kingdom
SR5 1NB

Study participating centre
Castleside Day Unit
Centre for Health of the Elderly
Campus for Ageing & Vitality
Westgate Road

Newcastle-Upon-Tyne
United Kingdom
NE4 6BE

Study participating centre
CRESTA Clinic
Biomedical Research Building
Campus for Ageing & Vitality
Westgate Road
Newcastle-Upon-Tyne
United Kingdom
NE4 6BE

Study participating centre
Campus for Ageing and Vitality
Belsay Unit
Westgate Road
Newcastle upon Tyne
United Kingdom
NE4 6BE

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type

Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon reasonable request from john.obrien@newcastle.ac.uk following the final publication of study analyses. Subject level anonymised data are available, and subjects provided consent for data sharing.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	23/09/2020	Yes	No
Results article		01/07/2021	13/02/2024	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Secondary analysis	17/08/2021	13/02/2024	Yes	No
Protocol file	version 5	07/06/2018	26/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes