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Can a Nurse Specialist improve care for people with memory problems now and in the future?

Submission date
23/01/2017

Recruitment status
No longer recruiting

Registration date
07/02/2017

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Currently one in three people aged over 60 years die with dementia. People in the advanced stages of dementia experience similar symptoms to those dying with cancer yet research shows that professional carers have difficulties in providing end of life care to people with dementia (PWD). Symptoms such as pain, agitation or low mood are common but may not be recognised or treated effectively. Most PWD would prefer to die in their usual place of care, but a significant proportion die in hospital. To improve quality of care and help people to die where they wish, it is crucial to explore more effective, integrated models of care. This study is looking at using a Dementia Nurse Specialist, selected resources and a core treatment team to promote change. The Dementia Nurse Specialist will support PWD who are approaching or planning for the end of life and their friend/family carers and to develop capacity and skills among community health and social care staff (e.g. GPs, district nurses and care home staff). The core treatment team will provide comprehensive support to the Dementia Nurse Specialist and facilitate links with existing services. The aim of this study is to look at how the Dementia Nurse Specialist fits into existing services and to collect data to inform a future larger trial.

Who can participate?
People with dementia (PWD) and their carers.

What does the study involve?
Participating GP practices are allocated to one of two groups. Participants attending practices in the first group receive care and support from a Dementia Nurse Specialist. The frequency of the support is tailored to the needs of individual participants. Participants attending practices in the second group receive usual care for the duration for the study. All participants with dementia their carers are followed for up 12 months, using a series of questionnaires administered every four months.
Participants who have taken part are also invited to participate in an additional series of interviews and observations. This involves the interaction of the participant with dementia, and /or family carer, with the dementia nurse specialist and/or healthcare professional being observed by researchers.

What are the possible benefits and risks of participating?
PWD and friend/family carers in intervention sites may benefit from the program. There are often few opportunities for PWD, their friend/family carers and staff providing care to engage in research and to reflect on their thoughts, feelings and opinions. Participation in the project would allow them to explore any issues they feel are relevant with an impartial individual, which may benefit the participants and could be a valuable experience allowing them to discuss issues and decisions that are concerning them with a neutral party and potentially empowering them to seek additional information or support. Bereaved friend/family carers may also welcome the opportunity to speak about their experiences.
While all participants may have limited benefit themselves from participating in the study, their participation may contribute to improving the quality of care received by other PWD, and enhancing the support received by friend/family carers in the future. The number of questionnaires to be completed may be a burden for participants. However, participants will be informed that for their comfort or convenience, they can take a break, postpone or reschedule the visit or complete the questionnaires over a number of sessions. Similar flexibility will be offered in relation to the qualitative interviews conducted for the process evaluation. The voluntary nature of participation will be emphasised. There is also a risk that observation of care may be intrusive for PWD and friend/family carers.

Where is the study run from?
1. Hexham Primary Care Centre (UK)
2. The Bondgate Practice (UK)
3. Saville Medical Group (UK)
4. Collingwood surgery (UK)

When is the study starting and how long is it expected to run for?
April 2016 to September 2018

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

Who is the main contact?
Professor Louise Robinson
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Contact information

Type(s)
Scientific

Contact name
Prof Louise Robinson

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Additional identifiers

Protocol serial number
31761

Study information

Scientific Title
SEED Workstream 4: A feasibility study of the supporting excellence in end of life care in dementia intervention

Acronym
SEED WS4

Study objectives
The aim of this study is to explore how an evidence-based intervention comprising a Dementia Nurse Specialist selected resources and a core intervention team to promote change fits into existing services and to collect data to inform a future definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 1 Research Ethics Committee, 16/01/2017, ref: 16/NE/0356

Primary study design
Interventional

Study design
Non-randomised; Both; Design type: Process of Care, Management of Care, Qualitative

Study type(s)
Treatment

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

Interventions
Pilot Trial:
GP practices are allocated to one of two groups, at ratio of 1:1.

Intervention Group :
The intervention is care and support from a Dementia Nurse Specialist. Participants with dementia, and family carer participants, will receive the intervention. The frequency of the intervention will be tailored to the needs of individual participants.

Control Group :
Participants with dementia, and family carer participants, will receive usual care for the duration for the study.

All participants with dementia, and family carer participants, will be followed for up 12 months, using a series of questionnaires administered every 4 months.

In both arms, where the person with dementia, or the family member, are unable to complete questionnaires, key informants and/or healthcare professionals will be invited to give consent to complete questionnaires on their behalf.

Process Evaluation:
Participants who have consented to take part in the pilot trial will also be invited to participate in an additional series of interviews and observations. This involves the interaction of the participant with dementia, and/or family carer, with the dementia nurse specialist and/or healthcare professional being observed by researchers. The researchers may take notes or audio record the interactions. Healthcare professionals as participants may also be observed during their interactions with the dementia nurse specialist. Researchers may take notes or audio record these interactions.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate is measured using the number of eligible participants who consent to participate in the study by 12 months
2 Retention rate is measured as the number of participants who consent to participate that remain in the study until the end of follow up at 12 months, or until they die (whichever is sooner).
3. Acceptability and engagement with the intervention and trial procedures

Key secondary outcome(s)
1. Health status is measured using EQ-5D-5L questionnaire at baseline, 4, 8 and 12 months, and 2 months after the death of the person with dementia
2. Health status is measured using EQ-5D-5L Proxy questionnaire, completed by family member of key informant at baseline, 4, 8 and 12 months
3. Anxiety and depression in family members is measured using HADS questionnaire at baseline, 4, 8 and 12 months and 2 months after the death of the person with dementia
4. For the participant with dementia, use of health care and personal social services is measured using a modified version of the Client Services Receipt Inventory (CSRI) questionnaire at 4, 8 and 12 months
5. For the participant who is a family member of the person with dementia, use of their own health care and personal social services is measured using a modified version of the Client Services Receipt Inventory (CSRI) questionnaire at 12 months and 2 months after the death of the person with dementia
6. Quality of life in people with advanced dementia is measured using the QUALID questionnaire at baseline, 4, 8 and 12 months
7. Common behavioural disturbances in dementia is measured using the Neuropsychiatric Inventory (NPI) questionnaire at baseline, 4, 8 and 12 months
8. The severity of nursing needs in the person with dementia will be measured using the Bedford Alzheimer Nursing Severity Scale (BANS-S) at baseline, 4, 8 and 12 months

9. Pain in non-communicative patients will be measured using the Pain Assessment in Advanced Dementia (PAINAD) questionnaire at baseline, 4, 8 and 12 months
10. Symptoms and conditions of the person with dementia during the last 7 days of life is measured using the CAD-EOLD questionnaire, completed by a family member 2 months after death
11. Nine end of life symptoms during the previous 90 days will be measured using the Symptom management at the end of life in dementia (SM-EOLD) questionnaire at baseline, 4, 8 and 12 months
12. Satisfaction with care, involvement in decision making and care planning will be measured using the Satisfaction with terminal Care in End of Life Dementia (SWC-EOLD) questionnaire at baseline, 4, 8, 12 months, and 2 months after the death of the person with dementia

Completion date
30/09/2018

Eligibility

Key inclusion criteria
Inclusion Criteria for the Pilot Trial:
People With Dementia
1. People on the dementia register who received a diagnosis of dementia in the last two years
2. People who are on both the dementia and palliative care registers
3. People on the dementia register who are considered to be within 12 months of end of life as judged by a member of the clinical care team

Carers
1. Main family member of the above participant with dementia
2. Age 18 years or over

Key informants
Key informants of participating people with dementia will be health or social care participant with dementia and able to report on quality of life, behavioural and psychological symptoms of dementia, symptom management, etc.

Inclusion criteria for process evaluation
1. Participants with dementia who have consented to participate in the pilot trial and agreed to contact by the qualitative research team
2. Family members of participants with dementia recruited to the study who have consented to participate in the pilot trial and agreed to contact by the qualitative research team
3. Health and social care professionals linked to intervention sites who provide end of life care to participants with dementia and their families
4. Members of the core intervention team
5. Members of the primary care team most closely involved in screening and study recruitment in control sites.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Patients with Dementia:
1. Under the age of 18 years
2. Judged as inappropriate for the study by a member of the primary care team (e.g. due to concurrent life events such as bereavement)
3. Not fluent English speakers
4. Not consenting to be contacted by the qualitative team during the initial trial consent process (process evaluation only)
5. Lack of capacity to consent (process evaluation)

Carers:
Not consenting to be contacted by the qualitative team during the initial trial consent process (process evaluation only).

Exclusion criteria for process evaluation
1. Participants with dementia and/or family members who do not consent to contact by the qualitative team during the initial pilot trial consent process
2. Potential participants who refuse consent
3. Any individuals under the age of 18 years

Date of first enrolment
01/03/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hexham Primary Care Centre
Burn Brae Medical Group
Corbridge Road
Hexham
United Kingdom
NE46 1QJ

Study participating centre
The Bondgate Practice
Infirmary Close
Alnwick
United Kingdom
NE66 2NL

Study participating centre
Saville Medical Group
7 Saville Place
Newcastle upon Tyne
United Kingdom
NE1 8DQ

Study participating centre
Collingwood surgery
Hawkeys Lane
North Shields
United Kingdom
NE29 0SF

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

ROR
https://ror.org/01gfeyd95

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 analysed during the current study will be available upon request from Professor Louise Robinson a.l.robinson@newcastle.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	27/11/2020	Yes	No
HRA research summary			26/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes