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PriDem: best practice in primary care led dementia support

Submission date
30/11/2021

Recruitment status
No longer recruiting

Registration date
08/12/2021

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning. Research has highlighted the urgent need for good quality, accessible and equitable post-diagnostic dementia care and support in England. This need has intensified recently due to the COVID-19 pandemic. National guidance summarises evidence-based best practice for post-diagnostic dementia support, but lacks practical advice on how to implement this. The PriDem study aims to develop and deliver accessible, feasible, sustainable primary care-based, post-diagnostic dementia care and support to people with dementia and their families. The ultimate aim is to reduce geographical inequalities in dementia care. In the earlier stages of the PriDem study, previous research and national practice have been explored through a literature review, survey, interviews and in-depth case studies. The findings were then used to develop the PriDem intervention alongside key stakeholders, including people living with dementia, carers ad professionals. The PriDem intervention will be situated within primary care networks (PCNs) and includes a Clinical Dementia Expert who will collaborate with primary care teams to improve local services. The Clinical Dementia Expert will support non-specialists to deliver dementia care and support, improve systems for delivery of evidence based, post diagnostic support and provide personalised care and support plans to meet the complex needs of with people living with dementia and their informal carers.

Who can participate?
This part of the PriDem study (Workstream 4) involves recruiting people living with dementia, their carers and professionals

What does the study involve?
This part of the PriDem study (Workstream 4) investigates feasibility i.e., is the intervention feasible and acceptable, and are the research processes feasible and realistic? It also investigates the factors that might support or hinder implementing this intervention in everyday practice. The researchers will test out the intervention in practice in a small number of Primary Care Networks – two in the Southeast and two in the Northeast of England. A Clinical Dementia Expert will work within the PCN and GP practices. People living with dementia and their carers will be recruited from the practices and asked to complete questionnaires related to wellbeing at the start of the study, and at 4 and 12 months. Interviews with participants will allow

researchers to gain insights into their experiences of receiving or delivering dementia care and support. There will also be an audit of care notes of people with dementia from participating GP practices, to look at whether there is an increase in personalised care plans throughout the intervention period.

What are the possible benefits and risks of participating?
Contributing to the study will help future individuals living with dementia to receive improved care. By testing this approach to care, the researchers can see how it will work in practice, how they could improve it, and if they should recommend it being more widely used.
Talking about healthcare experiences can be tiring and possibly distressing. the research team are aware of this and will regularly check with participants if they feel alright to continue, or otherwise would like to take a break (e.g., from an interview)

Where is the study run from?
University College London, in collaboration with Newcastle University (UK)

When is the study starting and how long is it expected to run for?
October 2020 to July 2023

Who is funding the study?
Alzheimer's Society (UK)

Who is the main contact?
Dr Sarah Griffiths
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Contact information

Type(s)
Scientific

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Dr Sarah Griffiths

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
294881

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50252, IRAS 294881

Study information

Scientific Title
Primary care led post-diagnostic dementia care: Feasibility and implementation study of evidence-based, person-centred sustainable models for future care

Acronym
PriDem

Study objectives
This feasibility and implementation study hypothesizes that a dedicated clinical dementia expert will be able to improve the care experienced by people living with dementia and their carers within primary care, by improving care planning, upskilling professionals and mapping local services.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 20/09/2021, Wales REC 4 (Address: not available; +44 (0)7976 982591, +44 (0)2920 230457; Wales.REC4@wales.nhs.uk), REC ref: 21/WA/0267

Study design
Interventional non-randomized study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Dementia

Interventions
In order to test the intervention, primary care networks will be provided with a Clinical Dementia Expert (employed by University College London) who will work with the local team to formalise primary care-led systems to support post-diagnostic support and care for people living with dementia and their carers. The intervention is designed to deliver tailored care through ongoing holistic review and care planning and to provide a tiered system of support, as well as building capacity and capability to ensure that non-specialist staff have the skills and knowledge to provide best practice post-diagnostic support to people with dementia and their families.

This will involve working with the primary care network staff and associates, through individual or team meetings, mapping current services, reviewing current pathways of care, and integrating evidence-based care practices that will be provided as part of the intervention.

During the implementation phase, a range of professionals (e.g., health care professionals and commissioners) will be invited to participate in two audio-recorded qualitative interviews (one at 4 months and one at 12 months – lasting 30-60 minutes) that will explore their experience of the intervention and potential barriers and facilitators to implementation.

People living with dementia and their carers will be invited to participate to provide information on the feasibility and implementation of the new model of care. The research team have worked with the PriDem Dementia Care Community (DCC), an inclusive stakeholder group bringing together people with dementia, family members, and representatives, to decide specific timings and numbers of research meetings and ensure that research aims are met without overburdening participants.

The person with dementia and carer (where consented) will be interviewed and will complete questionnaires at the start of the study (baseline). These consent and interview meetings may vary in duration depending on the participants' needs but may take up to 90 minutes (30 minutes consent and 60 minutes questionnaires) for carers and up to 1 hour (30 minutes consent and 30 minutes questionnaires) for the person with dementia, including breaks. This may be split over more than one visit, and may take place with the person with dementia and carer separately or as a dyad, depending on participants' preferences and abilities. Researchers will approach these visits in a flexible person-centred way.

The person living with dementia and the carer will be asked to complete the measures with a researcher individually, either in person, at their home or a different neutral location, or remotely (via telephone or video call), depending on the social restrictions at the time and the preferences of the participants. The questionnaires are validated measures, specifically designed for people living with dementia and their carers, to explore their well-being and quality of life. Later on in the study, researchers will follow up people with dementia and carers again, to complete the same questionnaires, at 4 months and 12 months = three researcher visits to complete interviews/questionnaires over the course of the study.

At 4 and 12 months, at the beginning and end of the implementation phase, a sample of people with dementia and carers, who indicated that they would be happy to do so when consented at baseline, will also be offered the opportunity to participate in one audio-recorded qualitative interview that will explore the provision of dementia-related care they have received and expect to receive from their primary care professionals. This interview is likely to last between 45 minutes and one hour.

Data collection not involving direct participant contact:
Researchers with appropriate research governance approvals will extract data from patient medical records in order to assess primary outcomes of the study (i.e., the number of people on dementia registers in participating GP practices who have personalised care plans and have received dementia reviews). This audit will take place at baseline and 12 months.

Intervention Type
Behavioural

Primary outcome(s)
Presence/absence of a personalised care plan: a binary measure of whether or not a recruited person with dementia has a personalised care plan in place, measured at 0 and 12 months

Key secondary outcome(s))
1. Health-related quality of life for the person living with dementia measured by the DEMQOL, EQ5D-5L, DEMQOL-Proxy and EQ5D-5L proxy at 0, 4 and 12 months
2. Service use measured by the Client Service Use Inventory-adapted for PriDem at 0, 4 and 12 months
3. Psychopathy in the person living with dementia measured by the Neuro-Psychiatric Inventory at 0, 4 and 12 months
4. Carer anxiety and depressions measured by the Hospital Anxiety and depression scale at 0, 4 and 12 months
5. Carer quality of life measured by the C-DEMQOL and EQ5D-5L at 0, 4 and 12 months

Completion date
18/07/2023

Eligibility

Key inclusion criteria
People living with dementia (PLWD):
1. Age 18+ years
2. Diagnosis of dementia recorded in patient medical record
3. Registered with a participating practice
4. Community-dwelling

5. Capacity to consent to the study. Where a patient does not have capacity to content, a consultee opinion will be sought

Carers:
1. Age 18+ years
2. Identified as a carer of a PLWD. A ‘carer’ is someone who gives care and support to their partner, child, friend, or another close relative. 'Care and support' can mean practical help or emotional support
3. Willing and able to provide informed consent (and acting as a consultee for the PLWD, if applicable)

Professionals:
1. Age 18+ years
2. Identified as working for or with PLWD
3. Willing and able to provide informed consent

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
60

Key exclusion criteria
People living with dementia (PLWD):
1. Individuals under the age of 18 years
2. Potential participants who are judged as inappropriate for the study by a member of the primary care team (e.g., due to concurrent life events such as bereavement or receiving end of life care)
3. Participants who have an advance statement recorded in their primary care records indicating that they do not wish to take part in research studies
4. People living in a care home

Carers:
1. Individuals under the age of 18 years
2. Potential participants who are 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. Participants who are not fluent English speakers will be excluded since they would be unable to complete the standardised outcome measures and are likely to have difficulties in participating in a qualitative interview

Professionals:
1. Health care professionals who do not provide post-diagnostic dementia support

Date of first enrolment
21/02/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Barnet Health Centre
149 E Barnet Rd
New Barnet
London
United Kingdom
EN4 8QZ

Study participating centre
Brunswick Park Medical Practice
Brunswick Park Rd
London
United Kingdom
N11 1EY

Study participating centre
Oakleigh Road Clinic
280 Oakleigh Rd N
London
United Kingdom
N20 0DH

Study participating centre
Throckley Medical Group
Tillmouth Park Rd
Throckley

Newcastle upon Tyne
United Kingdom
NE15 9PA

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

Study participating centre
Roseworth Surgery
27-29 Roseworth Avenue
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 1NB

Study participating centre
The Surgery-osborne Road
200 Osborne Road
Jesmond
Newcastle upon Tyne
United Kingdom
NE2 3LD

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Alzheimer's Society

Alternative Name(s)
alzheimerssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The researchers will be able to share the quantitative datasets on request but not the qualitative data, which will be pseudonymised rather than anonymised. The contact is Prof. Greta Rait (g.rait@ucl.ac.uk). Participants have consented to their quantitative data being shared with other researchers. Requests to use data will be submitted on a standard form and reviewed by a committee prior to data-sharing agreements being developed.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/07/2024	09/07/2024	Yes	No
Results article	Feasibility and acceptability findings	13/07/2024	16/07/2024	Yes	No
Protocol article		18/08/2023	21/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.0	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		16/01/2023	12/09/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes