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Evaluation of the Dementia-Personalised Care Team intervention for individuals with dementia and carers

Submission date
17/11/2021

Recruitment status
No longer recruiting

Registration date
13/12/2021

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is a set of symptoms that includes short-term memory loss, problem-solving difficulties and communication problems. Such symptoms worsen over time. Currently, over 850,000 people in the UK live with dementia. The burden for people diagnosed with dementia and their carers is substantial. People with dementia and their carers often find accessing support services stressful and challenging. Access to a single person, to help with the coordination of care throughout the dementia journey, is strongly desired.
This study aims to find out whether Dementia Support Workers (DSWs), based in GP surgeries, are a good way to support people. In a previous study, the researchers developed and tested an intervention for people with dementia and carers. They now want to understand how D-PACT should be delivered in various settings, including those often overlooked in dementia research, such as South Asian communities, impoverished coastal communities and individuals with no carer at home.

Who can participate?
Patients who have a diagnosis of dementia. Information will be sent out to potential participants who are identified by the GP practices taking part in the study. A main carer will also be recruited to the study wherever possible.

What does the study involve?
Participants will receive a dementia support worker for roughly 12 months to identify issues that are personally important to them. The carer is not forgotten; their priorities are taken into account too. The DSW won't tell participants what to do. Instead, the DSW will help participants plan things to improve physical and mental well-being. This might include how to access available services, and 'thinking ahead' to the future. Researchers will invite participants for an interview at several points throughout the study, in order to understand their experiences. Participants will be asked to take part in audio-recorded interviews with a researcher about their experience of D-PACT, and to complete a set of questionnaires when they join and again at 6 and

12 months. Some participants will complete a diary to document their D-PACT experience, and some will be asked for their permission to have some of their sessions with the DSW audio recorded for analysis.

What are the possible benefits and risks of participating?
It is hoped that the study will help lead to a better understanding of how we can improve future support. It is possible that carrying out questionnaires and assessments at the beginning and end of the study might feel challenging or upsetting for some people. Researchers are experienced and sensitive to this and will adapt their process where needed.

Where is the study run from?
The study is run across two UK sites: South West (Devon Partnership Trust) and North West (Pennine Care NHS Foundation Trust). The South West is the lead site.

When is the study starting and how long is it expected to run for?
May 2021 to January 2024

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

Who is the main contact?
Prof. Richard Byng
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
302690

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50334, IRAS 302690

Study information

Scientific Title
Realist informed mixed-methods evaluation of the Dementia-Personalised Care Team intervention (D-PACT): a complex intervention for individuals with dementia and carers

Acronym
DPACT2

Study objectives
The Dementia Personalised Care Team Programme (D-PACT) is a National Institute of Health Research (NIHR) Programme Grant for Applied Research (PGfAR) funded programme that aims to determine the most effective deployment of dementia support personnel in primary care. In the initial feasibility study the intervention theory and inclusive recruitment methods were developed, as well as the selection of outcome measures. The D-PACT2 study aims to achieve an enhanced understanding of the D-PACT intervention delivery by:
1. Understanding how the D-PACT intervention is – and should be – delivered in varied settings

and further refine programme theory
2. Providing evidence about the potential value and impact of the D-PACT intervention
3. Contributing to the methodological development of community-based dementia studies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/10/2021, South Central Berkshire Research Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048224; berkshire.rec@hra.nhs.uk), REC ref: 21/SC/0280

Study design
Non-randomized; Both; Design type: Treatment, Process of Care, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical, Management of Care, Active Monitoring, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Potential participants will be approached by letter in the first instance. If there is no response to this invitation to take part, further approaches are made, in stages, which include a telephone call and home visit, where applicable. Potential participants who decline participation will be offered a short interview with a researcher to explore their reasons for declining - this is optional. Potential participants who then express an interest in participating to the researcher (as well as those potential participants who have self-referred to the researcher via word of mouth) will be provided with the Participant Information Sheet and Further Information Sheet and offered a meeting with the researcher (Study Involvement Meeting).

A member of the research team who is knowledgeable about the research will discuss the study with the potential participant. If the individual with dementia is eligible and agrees to participate in the study, the researcher and the individual with dementia will complete the approved Informed Consent Form. Similarly, if the carer agrees to participate in the study, the researcher and the carer will complete the approved Informed Consent Form. Should the individual with dementia lack the capacity to give informed consent, and the designated consultee (usually the carer participant) considers that the individual with dementia would want to take part, the researcher and the consultee will complete the Consultee Declaration Form.

Participants with dementia will be asked to:
1. Complete demographics data collection with the researcher at baseline
2. Complete as assessment of cognition (MoCA) with the researcher at baseline
3. Take part in semi-structured interviews with a researcher at a minimum of one timepoint (but up to three) throughout their participation in the study
4. Keep and share with the researcher a reflective diary (in the form of either photos, texts or

audio or written diary). This is optional
5. Have some selected DSW-participant interactions and follow-up feedback calls audio-recorded by the researcher. This is a sub-set of participants
6. Allow certain health care record data to be captured (general practice and Dementia Support Worker records)
7. With the researcher, complete a set of questionnaires at baseline, 4-6 months and 9-12 months, comprised of:
7.1. A measure of experience of care (PERCCI)*
7.2. Supplementary questions to the PERRCI*
7.3. A measure of positive outcomes (EID-Q)*
7.4. Supplementary questions to the EID-Q*
7.5. A quality of life measure (EQ-5D-5L)*
7.6. A health and social care resource use survey*
*If the individual is unable to self-report, the carer will be asked to act as a proxy for the individual with dementia.

Carer participants will be asked to:
1. Take part in up to three semi-structured interviews with a researcher throughout their participation in the study
2. Keep and share with the researcher a reflective diary with the individual with dementia (in the form of either photos, texts or audio or written diary). This is optional.
3. Have some selected Dementia Support Worker-participant interactions and follow-up feedback calls audio-recorded by the researcher. This is a sub-set of participants.
4. With the researcher, complete a set of questionnaires at baseline, 4-6 months and 9-12 months, comprised of:
4.1. Carer Wellbeing and Support questionnaire
4.2. A health and social care resource use survey
4.3. A measure of experience of care (PERCCI)*
4.4. Supplementary questions to the PERRCI*
4.5. A measure of positive outcomes (EID-Q)*
4.6. Supplementary questions to the EID-Q*
4.7. A quality of life measure (EQ-5D-5L)*
4.8. A health and social care resource use survey*
*as a proxy for the individual with dementia when a proxy is needed

Participants with dementia and carer participants will be offered the intervention for 12 months.

Dementia Support Workers will be asked to:
1. Keep and share with the researcher a reflective diary (in the form of either photos, texts or audio or written diary). This is optional
2. Take part in semi-structured interviews with a researcher throughout the study
3. Have some sessions with their supervisor audio-recorded by the researcher
4. Have selected DSW-participant interactions and follow-up feedback calls audio-recorded by the researcher
5. Share certain records and notes pertaining to intervention delivery with the researcher
6. Be shadowed by the researcher at GP surgeries, Primary Care Network meetings and multi-disciplinary team meetings relevant to intervention delivery/participants
7. Provide timesheets relevant to the study/intervention delivery to the researcher

GP staff, other practitioners, and team leaders, in other services relevant to the study will be asked to take part in a semi-structured interview with a researcher about their perceptions of, and interactions with, the Dementia Support Workers, participants and the intervention.

Intervention Type
Behavioural

Primary outcome(s)
The study will mainly be collecting people with dementia and carers' experiences and perceptions of the support they have received from the D-PACT DSW and what changes it has led to in their lives, collected using realist qualitative interviews at 4-6 months and 9-12 months follow-up.

The study does not have a primary outcome measure, but the following quantitative data will be collected:
1. Engagement and independence measured using the Engagement and Independence in Dementia Questionnaire (EID-Q) at baseline, 4-6 months and 9-12 months
2. Care experience measured using the Person Centred Community Care Inventory (PERCCI) at baseline, 4-6 months and 9-12 months
3. Quality of life for both the individual with dementia and carer measured using the EuroQol (EQ-5D-5L) at baseline, 4-6 months and 9-12 months
4. Carer wellbeing measured using the Carer Wellbeing and Support Questionnaire (CWS) at baseline, 4-6 months and 9-12 months

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. People with a clinical diagnosis of dementia, and their carers if applicable:
1.1. Dementia is a broad term used to describe a range of neurodegenerative disorders which may include but will not be limited to: Alzheimer's disease (AD); late-onset Alzheimer's disease (LOAD); early onset Alzheimer's disease (EOAD); vascular dementia (VAD); mixed dementia (AD with VAD); dementia with Lewy bodies (LBD); frontotemporal dementia (FTD); Parkinson's disease dementia (PDD)
1.2. Carers in this context are unpaid and are defined as the primary person who feels responsible for and supports the person with dementia

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
247

Key exclusion criteria
1. Those who are resident outside the local authority boundary to be served
2. Those currently undergoing emergency treatment or care. (however, a delayed second approach will be attempted, if appropriate, if the person returns home within the timeframe of the research recruitment)
3. Those within care home setting
4. Those receiving substantial support from Community Mental Health Teams (CMHT), defined as input within the last four months and not due to be discharged within the next 2 months
5. Those who present as high risk and, after referral, are taken on by CMHT
6. Those with open safeguarding referrals and ongoing planned CMHT care
7. Those with a longstanding history of mental health difficulties and currently receiving care from other mental health team
8. Diagnosed with an end-stage physical health problem (e.g. cancer, severe heart failure) with substantive multi-disciplinary palliative and/or end-of-life care in place
9. Clinically qualified decision

Date of first enrolment
01/01/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
University of Plymouth
Drake Circus
Plymouth
United Kingdom
PL1 4AA

Study participating centre
University of Manchester
Ellen Wilkinson Building
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United Kingdom
M13 9PL

Sponsor information

Organisation
Devon Partnership NHS Trust

ROR
https://ror.org/04fkxrb51

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0217-20004

Results and Publications

Individual participant data (IPD) sharing plan
After the results of the study have been published, the individual participant-level data that underlie the results will be available on request from the Chief Investigator (CI), Prof. Richard Byng (D-PACT@plymouth.ac.uk) and Sponsor, along with supplementary files as required (e.g. data dictionaries, blank data collection forms, analysis code, etc). Data will be shared with (or access to the data will be provided to) requestors whose proposed use of the data has been

approved by the CI and Sponsor, under an appropriate data sharing agreement. It will not be possible to identify participants personally from any information shared.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes