ISRCTN80204146 https://doi.org/10.1186/ISRCTN80204146

DPACT dementia support study

Submission date
02/09/2019

Recruitment status
No longer recruiting

Registration date
23/09/2019

Overall study status
Completed

Last Edited
18/12/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia-Person Aligned Care Team (D-PACT) is a research study looking at support workers for people with dementia. At the moment, there are several types of dementia support roles (e.g. Dementia Support Workers; Dementia Navigators; Dementia Advisors). These workers are often highly valued, although the type of work they do differs depending on where they are based and who funds them. Also, little is known about which aspects of support are the most effective. There are indications based on previous studies that the best place for a support worker to be based in a GP practice. The D-PACT study aims to find out the most effective way that a support worker based in a GP practice can support people with dementia and their carers to maintain their health and emotional wellbeing, to plan for the future, to ensure their values and preferences are understood, and to prevent avoidable hospital admissions. There are two main phases to D-PACT. This summary is about the first phase of D-PACT which includes a feasibility study.

Who can participate?
People who have a diagnosis of dementia or who have significant memory difficulties. 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 feasibility study involve?
The first two years of this study make up a ‘developmental’ phase. During these two years the researchers are developing a dementia support worker role based on the elements that are most likely to be effective. This is known as an ‘intervention’ where they determine what the worker will do and how they will work alongside existing services. The researchers have done some of this work already based on evidence from the literature and from knowledge gained through interviewing people living with dementia, carers, existing support workers and other experts. Also as part of the developmental phase, they will run a feasibility study over a period of a year. This involves trying out the intervention in three GP practices in the South West and three in the North West (up to 40 participants with dementia in each site). They will compare this to one GP practice in each site that does not have a support worker (up to 15 participants in each site). During the feasibility study, all those who consent to participate will be asked to participate in some questionnaires/assessments to indicate areas that are going well or not so well. They will be asked to complete these at the beginning and end of the feasibility study. Participants will then either receive a dementia support worker or will receive their usual care.

The dementia support worker will act as a single point of contact, working with people to help identify what matters to them, what areas could be strengthened and where there may be new opportunities to explore. Support workers will provide information that is timely and tailored to the person. They will also collaborate across health, social care and community resources, in order to draw in support based on individual need. Researchers will interview some of those receiving the intervention and some of those who are not, at several points throughout the feasibility study, in order to understand their experiences.

What are the possible benefits and risks of participating?
The results of the feasibility study will help to show whether the intervention is practical and acceptable to people living with dementia and practitioners. Also, the researchers will find out how best to scale up the research for the next phase, in which they aim to run a trial over three years with a larger number of GP practices. During the trial phase they will be measuring the effectiveness of the intervention in terms of the improvement in quality of life for both people with dementia and carers, compared to those participants experiencing 'treatment as usual'. Those who receive a dementia support worker may benefit from receiving individualised care. All those participating will be contributing to furthering an understanding of how best people living with dementia can be supported. 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 (Cheshire and Wirral Partnership Trust). The South West is the lead site.

When is the study starting and how long is it expected to run for?
November 2018 to June 2022

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

Who is the main contact?
Prof. Richard Byng
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Study website
https://www.plymouth.ac.uk/research/primarycare/dementia-person-aligned-care-team

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS: 42963

Study information

Scientific Title
Dementia Person-Aligned Care Team (DPACT)

Acronym
DPACT

Study objectives
The Dementia Person Aligned Care Team Programme (DPACT) 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 order to:
1. Maintain the health and wellbeing of people with dementia and their carers/families through a person-centred approach to care delivery.
2. Facilitate proactive anticipatory care and therefore shift costs from acute unplanned admissions to community-based provision in an overall affordable model of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2019, South Central Berkshire Ethics Committee (Easthamstead Baptist Church, South Hill Road, Bracknell, RG12 7NS, UK; Tel: +44 (0)207 104 8360; Email: Nrescommittee.southcentral-berkshire@nhs.net), REC ref: 19/SC/0264

Study design
Randomised; 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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Interventions
This Feasibility Study will develop a Dementia Support Worker (DSW) intervention and a recruitment approach. We will put these into practice in eight GP practices in order to learn how to improve the intervention and trial design for a later cluster randomised controlled trial. The whole process including recruitment and analysis will take approximately 15 months.

Practices and recruitment
110 people with dementia will be recruited to the study from 4 x GP practice at each of two UK sites (South West and North West). The sample size is detailed in section A59. Participants

recruited from the first practice at each site will receive the DSW intervention (to allow early learning to feed into revisions to the intervention for the other practices). Cluster randomisation process will be applied to the remaining 3 x GP practice at each site (to test acceptability of randomisation).

If a person with dementia (PwD) has a carer (such as a partner, family member or other trusted person who supports them on a day to day basis) they will also be asked to participate in the study.

The flexible person centred recruitment process for people with dementia and their carers is detailed in section 27-1. It involves combining electronic searches from primary and secondary care records, checking clinical records, sending letters of invitation, making calls and if clinically required a visit to a PwD's home. We will determine the
proportion of those likely to benefit recruited into the study, examine the experiences of recruitment and if required make revisions to the process which will require amendments to ethics and HRA.

Inclusion/Exclusion criteria: Individuals with dementia or likely dementia, specified in A17-1 and A17-2. Individuals recorded as not wanting to be part of research will be excluded.

Outcome Measures
In the feasibility study we will test the delivery of selected outcome measures and assess their acceptability. There will be a point of measurement pre- and post-intervention. We are mindful that using too many measures would place an unacceptable burden on participants so we are currently refining our choice of outcomes to allow for an
average of 90 minutes of assessment activity, depending on the participant's ability and fatigue. However, one aim of the feasibility work is to explore if and when completion of outcome measures becomes burdensome, through constant monitoring of participant responses and feedback. This will contribute to understanding the population and
guiding inclusion and exclusion criteria (contributing to the literature review and qualitative intervention work). Currently we are considering measures for the person with dementia: Quality of Life (DEMQOL); Activities of daily living (BADLS): neuropsychiatric symptoms (NPI).

Cognitive function: although not an outcome measure, cognitive ability will be assessed in order to ascertain the level of support needed by a person with dementia as well as providing participant information (ACE mobile/MMSE). We are also investigating potential carer outcomes (Carer Wellbeing and Support [CWS] Questionnaire).

Follow-Up
Structured face to face interviews will be carried out with the person with dementia and carer between 4 and 12 months after recruitment (to assess and optimise follow up procedures for main trial).

DSW Intervention
Phase 1 work aims to develop the optimum DSW approach. We have developed a theoretical intervention model.

Intervention Delivery
The DSW will be supervised by an experienced clinician and will employ a coaching approach to support PwD and carers. DSWs and supervisor will be trained to deliver the intervention according to a manual (current version uploaded for information).

The number and duration of contacts between DSW and person with dementia is flexible and will depend on the complexity of each case. However, it is likely that in this feasibility phase, the DSW will meet the person with dementia and carer together (if there is a carer involved) for an average of two hours initially. This will allow for initial information gathering and the beginnings of joint goal identification.

Intervention content
The assessment will cover key areas of health and social wellbeing. The number of subsequent contacts will be guided by the specific goals that have been agreed and will be highly individualised. We envisage that in this feasibility phase the number of subsequent contacts (including telephone) will be between one and ten, with a length of 15-90 minutes.

Recipients of the intervention will work with a Dementia Support Worker (DSW) who will:
• Take time to establish rapport with the person with dementia and carer. It will be necessary to establish engagement and a trusting relationship from the beginning. We know that some people with dementia and carers lack trust in healthcare providers, for instance they may have had a difficult journey through diagnosis or feel that there was limited explanation of the symptoms and prognosis. It will be important to demonstrate that the DSW is emphatic and non-judgemental. Being proactive in arranging follow-up sessions also demonstrates commitment and care.
• Work towards a shared understanding of the PwD's and carer's strengths, interests, values and preferences for their lives. This will involve listening to their accounts of their life experiences to the extent that they want to talk about them. It means trying to figure out, with them, what matters most to them amongst a range of potential issues.
• Use a coaching approach to unlock potential, identifying areas for change and creating a 'Shared Action Plan'. This will be achieved through an ongoing process of developing self-understanding and knowledge of potential strategies.
• Liaise between services (health, social and community) to influence teams, maintaining a focus around the goals in the shared action plan. Interactions will be documented in line with local systems.
• Proactively follow-up and provide opportunities to adapt the shared action plan depending on life circumstances.

Domains of possible importance for a person with dementia to be incorporated into the shared understanding and plan could include:
• Anticipatory care – planning ahead for changes in care or admissions
• Cognition - Memory and thinking, diagnosis, communication, driving
• Emotional Wellbeing - Positive emotions, mental health conditions, apathy, self-care, support systems, worries about future.
• Physical Wellbeing - Hearing and vision, health conditions, preventable conditions, new symptoms, medication management, self-care, frailty awareness of GP health review.
• Activation - Interactions with people, familiar places, activities engaged in.

Carer domains could include:
• Support network - Family and friends, practitioners, organisations/charities.

Formative evaluation of the intervention (how we will improve it ready for the trial).
The following data will be collected:
• Qualitative interviews will take place face-to-face at the end of the intervention testing phase and will last between 45-90 minutes dependent upon individual ability and levels of fatigue. A question guide will be refined prior to the interviews through analysis of the literature and

consultation with the Peer Research Group and Expert Review Group.
Participants will be sent an outline of the types of questions to be asked prior to the interview to allow time for reflection.
• A sample of DSW/PwD interactions will be recorded by video.
• A sample of 1-2 GPs, Practice Nurses and Practice Managers will be interviewed per practice.
• DSWs and Supervisors will be interviewed 2-3 times each.
• Written records of intervention delivery made by the DSW (checklist of components use for each PwD, Qualitative Commentary on perceived benefits).

Data will be transcribed verbatim, with every effort made to ensure that individuals are not identifiable in the transcript. Data will be analysed using a Framework Analysis approach to identify how to improve the intervention. NVivo software will be used to support the data organisation and analysis. All data will be stored on password protected and encrypted computers.

Data protection:
The study personnel and co-investigators will ensure that the study is conducted within the appropriate NHS and professional ethical guidelines. Information will be kept strictly confidential and held in accordance with Data Protection Act (1998) and EU General Data Protection Regulation (2018). Appropriate access controls will be in place to ensure that access to confidential research information is restricted to those who require access.

Intervention Type
Other

Primary outcome measure
This is a feasibility study and as such there is no primary outcome. The proportion of individuals likely to have dementia recruited into the study is the key quantitative measure to be calculated. The primary outcome measure for the later main trial will be quality of life for the person with dementia and their carer.

Secondary outcome measures
The appropriateness of the specific outcome measures is one of the research questions which this study will address. The following outcome measures are potential candidates for key domains and will be collected during recruitment. The researchers will test out these as listed and these may change as a result of the research process and any changes will be subject to amendment:
1. Functional impairment measured using the Bristol Activities of Daily Living Scale (BADLS)
2. Behavioural and psychological symptoms measured using the Neuro Psychiatric Inventory (NPI)
3. Dementia-related quality of life measured using the Dementia Quality of Life scale (DEMQOL and DEMQOL-Proxy)
4. Carer well-being is measured using the Carer Well-being and Support (CWS) Questionnaire
5. Cognition measured using the Addenbrooke's Cognitive Examination (ACE) Mobile
Measured at baseline and 2-9 months

Overall study start date
01/11/2018

Completion date
01/06/2022

Eligibility

Key inclusion criteria
People living with dementia† (people with a formal diagnosis of dementia regardless of specific type) and significant cognitive problems which could indicate dementia and their carer‡, resident within the local authority boundary to be served. The programme also aims to investigate ways in which people with dementia without a carer can be included.

†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).

‡Carers in this context are defined as "the primary person who feels responsible for, and supports, the person with dementia". Inclusion criteria need to be constructed that do not exclude participants that are representative of the target population and stand to benefit most from the intervention. We need to avoid waste of resources and unnecessary burden on patients by not including those at a disease stage so mild that it precludes benefit. Inclusion criteria will require careful consideration from practical perspectives. Roughly one third of people with dementia live alone and while some may still have an active and engaged carer, it is likely that assistance received is more variable than in dyads where the carer is cohabitating. This may also influence engagement with a Dementia Support Worker intervention. There is also a higher trial dropout rate associated with people with dementia with non-spousal carers.

While the intention is to include such individuals in the trial, it will be necessary to explore the mechanisms of the intervention in the context of variable carer capacity and care-delivery; the proxy reporting capacity of the carer will need to be considered with regard to valid outcome completion. This is one of the key aspects of the intervention that the Peer Research Group will be engaged with.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 110; UK Sample Size: 110

Key exclusion criteria
Current exclusion criteria as of 27/10/2020:
1. Those who are resident outside the local authority boundary to be served
2. Those currently undergoing emergency treatment or care
3. Those within care home setting
4. Those who score mild or non-impaired a cognitive screening assessment

Previous exclusion criteria:
1. Those who are resident outside the local authority boundary to be served
2. Those currently undergoing emergency treatment or care
3. Those within care home setting

Date of first enrolment
19/07/2019

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: South West Peninsula
United Kingdom
PL6 8BX

Study participating centre
Okehampton Medical Centre
East Street
Okehampton
United Kingdom
EX20 1AY

Study participating centre
Castle Place Surgery
Kennedy Way
Tiverton
United Kingdom
EX16 6NP

Study participating centre
Clare House Surgery
Newport St
Tiverton
United Kingdom
EX16 6NJ

Study participating centre
Chiddenbrook Surgery
Threshers
Crediton
United Kingdom
EX17 3JJ

Study participating centre
Westminster Surgery
Church Parade
Ellesmere Port
Chester
United Kingdom
CH65 2ER

Study participating centre
Old Hall Surgery
24-26 Stanney Lane
Whitby
United Kingdom
CH65 9AD

Study participating centre
The Willaston Surgery
Neston Road
Willaston
United Kingdom
CH64 2TN

Study participating centre
Park Medical Center
Shavington Avenue
Newton Lane
Chester
United Kingdom
CH2 3RD

Study participating centre

Ashfields Primary Care Centre
19 Middlewich Road
Sandbach
United Kingdom
CW11 1EQ

Study participating centre
Kiltearn Medical Centre
Church View Primary Care Centre
Beam Street
Nantwich
United Kingdom
CW5 5NX

Sponsor information

Organisation
Devon Partnership NHS Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan

The researchers plan to disseminate the study in peer-reviewed journals and conferences, as well as the study website. A summary of findings will be sent to each of the study sites, and participants will be given the option of receiving a summary. The researchers intend to publish their results in September 2021.

Intention to publish date

30/04/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2.1	05/06/2019	23/09/2019	No	No
HRA research summary			28/06/2023	No	No