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Longitudinal realist evaluation of the Dementia PersonAlised Care Team (D-PACT) intervention: protocol

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ABSTRACT

Background: Different dementia support roles exist but evidence is lacking on which aspects are best, for whom and in what circumstance, and on their associated costs and benefits. Phase 1 of the Dementia PersonAlised Care Team programme (D-PACT), developed a post-diagnostic primary care-based intervention for people with dementia and their carers and assessed the feasibility of a trial.

Aim: Phase 2 of the programme aims to 1) refine our programme theory on how, when and for whom the intervention works and 2) evaluate its value and impact.

Design and setting: A realist longitudinal mixed-methods evaluation will be conducted in urban, rural, and coastal areas across Southwest and Northwest England where low-income groups or ethnic minorities (e.g. South Asian) are represented. Design was informed by patient, public and professional stakeholder input and Phase 1 findings.

Method: High volume qualitative and quantitative data will be collected longitudinally from people with dementia, carers and practitioners. Analyses will comprise: 1) realist longitudinal case studies; 2) conversation analysis of recorded interactions; 3) statistical analyses of outcome and experience questionnaires; 4a) health economic analysis examining costs of delivery; 4b) realist economic analysis of high-cost events and 'near misses'. All findings will be synthesised using a joint display table,

evidence appraisal tool, triangulation and stakeholder co-analysis.

Conclusion: Our realist evaluation will describe how, why and for whom the intervention leads (or not) to change over time; it also demonstrates how a non-randomised design can be more appropriate for complex interventions with similar questions or populations.

KEYWORDS: primary care, dementia, personalised care, realist evaluation

HOW THIS FITS IN

UK policy recognises the need for improved dementia care, post diagnosis. Dementia support workers are valued by people with dementia and carers, but their role and availability vary substantially. Decision-makers need evidence to support decisions on what type of dementia support to provide and to inform their workforce strategies. This evidence not only needs to detail what outcomes it achieves but also how it works, for whom and in what circumstances, as this will not only support commissioning decisions, but also effective implementation - enabling modification, where appropriate, to ensure underserved communities can also benefit. A primary care model of dementia support was developed for evaluation due to the desire and recognised need for coordinated, ongoing and collaborative care.

INTRODUCTION

The term 'dementia' describes a progressive set of symptoms that includes loss of short-term memory and problem-solving ability, communication problems and loss of visuospatial skills. Over 850,000 people in the United Kingdom (UK) live with dementia and at this rate is predicted to increase to around 1.1 million by 2025. With an ageing population and 72% of individuals who have dementia also living with another medical condition or disability, we can expect a significant impact on the National Health Service (NHS) and social care services.[1] The need to "deliver integrated and effective services that meet the needs of people with dementia and their families and carers" was set out by the UK Department for Health and Social Care, along with an ambition to ensure that appropriate evidence is available across health and social care on best practice in post-diagnostic care.[2] However, little is known about what kind of support is likely to be feasible, acceptable and have a positive impact, especially for historically underserved communities who may face even more barriers accessing services.[3]

Feedback from people with dementia and their informal carers suggests that current access to post-diagnostic dementia support and the model of support provided is extremely variable. They report often finding access to support services stressful and challenging and describe the "maze-like" services landscape, the limited and variable availability and remits of services, and the struggle to make headway.[4] People with dementia and informal carers have identified that they strongly desire

access to a single person, to aid the coordination of care throughout the dementia trajectory.[5-6]

There are a variety of dementia support roles within the NHS and Social Care services (Dementia Support Workers (DSWs); Dementia Navigators; Dementia Advisors), in different settings around the UK. While patients value these roles[7,8] there is lack of evidence as to the most effective aspects of support, who is most likely to benefit, where it would be best delivered and what the costs and the health benefits of these support roles might be.[2-5] Such information is needed by decision-makers (commissioners and providers) when considering whether to invest in these dementia support services. There is, therefore, a need to understand, in relation to the dementia support worker role, "what works, for whom, in what circumstances and why".[9]

Our 5-year Dementia PersonAlised Care Team (D-PACT) programme is funded by the National Institute for Health and Care Research (NIHR) to address these knowledge gaps. It has developed, and is about to evaluate, an intervention for people with dementia and carers that provides ongoing post-diagnostic support in the form of a dementia support worker, embedded within primary care (see Figure 1). A favourable opinion for this project was received from the South Central - Berkshire Research Ethics Committee for the D-PACT evaluation (Ref: 21/SC/0280).

INTERVENTION DEVELOPMENT

The D-PACT intervention development was designed to be conducted over two Phases, informed by the framework for realist evaluation proposed by Pawson and Tilley.[9]

Stage 1) (Development Phase)

a) Development of the initial programme theory (IPT) underlying the D-PACT intervention

b) Refinement of an elaborated programme theory (EPT) through piloting the intervention-in-development, and

Stage 2) (Evaluation)

Rigorous testing of the programme theory, with more participants in various settings, so resulting evidence can be used to corroborate, refute or extend the understanding of the EPT during analysis.

Completion of the two Phases will lead to a finalised version of the theory. The term 'finalised' refers to it being the last version of the programme theory that the project produces. It does not suggest that the theory cannot be enhanced further, through future studies. At the time of writing (January 2023), the first Phase has been completed, and the second Phase is in progress (due to be completed in February 2024).

A realist approach to evaluation

Realist evaluation is a form of theory-driven evaluation used to understand if, how, for whom and under what circumstances an intervention 'works' to produce intended outcomes.[9] It is increasingly used for complex care interventions due to the focus on understanding how interventions work for different people and why outcomes may or may not be attained in different contexts. Realist evaluations seek to uncover how intervention outcomes (O) are produced, by examining the mechanisms (M) intended to produce them and the various contexts (C) that interact to enable or constrain the mechanism taking effect.[9,10] The ways in which particular contexts and mechanisms produce outcomes are conceptualised in explanatory programme theories, commonly articulated through 'context-mechanism-outcome' (CMO) configurations. The CMO heuristic is often used as a framework in realist evaluation, transforming 'implicit' causal mechanisms into explicit programme theory statements. This guides what and how data are collected, the analytic process, and interpretation of evidence through the realist evaluation process. The programme theory (consisting of all the C-M-O statements) is developed iteratively, cycling between (1) theory development (i.e., generating a working theory/hypothesis), (2) theory verification (i.e., hypothesis/theory testing throughout data collection), and (3) theory refinement (i.e., refining the hypothesis/ theory based on emerging data).

EVALUATION AIMS

There are two core aims of the evaluation:

1. To test and refine the D-PACT programme theory to better understand:

    a) How various components (e.g. supporting disclosure; enhancing empowerment; developing shared understanding and facilitating collaboration with other professionals) of the delivered intervention work, in what context they work (e.g. stage of illness, organisational, cultural or geographical), for whom (i.e. people with dementia and their informal carers with diverse personal, socio-economic status, cultural understanding, circumstances) and what outcomes they generate (proximal and distal) for people with dementia and carers;

    b) How the facilitative actions supporting the delivery of the intervention (including training, supervision and peer support) work, when it works (e.g. in what organisational context) for whom (i.e. dementia support workers from diverse professional backgrounds, with different learning preferences etc.) and what outcomes they generate (proximal and distal) for dementia support workers.

    Figure 2, below, visualises how the two tiers of the programme theory intertwine to make the intervention work.

2. To examine the potential value and impact of the intervention.

Here we adopt the NHS Impact Framework's definition of value and impact, where "value" refers to the importance, worth or usefulness of the intervention and "impact" to the intervention having an effect, influence or resulting in changes, whether positive or negative (see also Westhorp, 2014).[11]

METHODS AND ANALYSIS

Study Design

Consistent with realist principles, a mixed-method approach to longitudinal data collection will enable us to test and refine the elaborated programme theory (EPT) and evidence both the proximal outcomes and distal outcomes of the intervention. The conduct and reporting of the evaluation will be guided by the Realist and Meta-Review Evidence Synthesis Evolving Standards (RAMESES II) reporting standards[12] and MRC.[13, 14]

of the study. Members of the project's Peer Research Group and professional stakeholders have informed[15] (and will continue to inform) the development of our research materials and processes.

Table 1 (please supplementary file 1) details the data sources for the evaluation. Data managers and trials managers at the Peninsula Clinical Trials Unit will have oversight of data captured at screening, recruitment, and baseline and in the Case report Files (CRFs) at follow-up. Central monitoring of data will be performed, to include assessments of participant recruitment rates, attrition rates, data

completeness, data quality and protocol non-compliance. Qualitative data will be stored and managed on a secure file saving platform, hosted at the University of Plymouth, which only research team members will have access to. Following completion of study data analysis, the Sponsor will be responsible for archiving the study data and essential documents in a secure location for at least five years after the end.

Setting

The aim is to recruit 18 GP practices across two geographical regions, the South West (SW) – specifically Devon – and North West (NW) – specifically Greater Manchester – of England. Selection criteria for these practices include:

- Interest in the project

- Localisation (urban, rural, and coastal areas across SW and NW England with higher representation of ethnic minorities particularly South Asian or communities with high deprivation)

- A reasonable number of patients on the practice's Quality and Outcomes Framework (QOF) dementia register.

Participants

People with dementia, their informal carers (if available and willing) and practitioners will be recruited. The latter group will comprise dementia support workers (n = minimum of 5), their supervisors (n = minimum of 4) and primary care staff members

(n = minimum of 15) from participating GP surgeries will have the opportunity to participate in interviews, observations and feedback sessions.

We plan to recruit up to 180 people with dementia and up to 160 informal carers. People with dementia without carers are eligible for this study, as are those who lack capacity to consent (an under-represented group in dementia studies). Figure 3 shows our other eligibility criteria. A minimum (n=90 people with dementia) to maximum (n=180) range was chosen for pragmatic reasons, including uncertainty about recruitment rates. In brief, the minimum sample size allows us to: have enough variety in terms of patient cohorts; fulfil requirements around the dementia support worker's (DSW's) caseload (45-55 patients). This figure was chosen based on three key criteria: (I) current dementia support worker caseloads (e.g. Weston, 2021[19]); (ii) the objective of testing delivery of D-PACT with people with a wide range of characteristics (socio-economic background, ethnicity, sex, dementia stage, frailty), the time it would take for DSWs to provide data to the evaluation and (iii) to test the intervention theory around team working (at least two DSWs) and peer support with various types of primary care networks (PCNs). Our minimum target takes account of likely participant attrition in a longitudinal study (involving people with dementia and in some cases, older carers), that aims to track changes over time and provides us with a more accurate measure of 'reach', e.g., the level of engagement of various groups which often miss out on care, and not just overall total.

The maximum recruitment will allow us to test the ability of DSWs to provide care at a higher caseload and would further enhance heterogeneity of participants in order

better to test intervention theory. Whilst the sample size was not calculated statistically, a sample of at least 90-180 participants was estimated to provide a robust assessment of baseline and follow up scores on measures.

Participants will be recruited either by (i) a proactive person-centred approach by embedded researchers, designed to reach as many people with dementia as possible (4-stage approach, described elsewhere (forthcoming manuscript)[20] and reduce the burden of recruitment on primary care; or (ii) responsive recruitment, where potentially eligible people with dementia can enquire about the study directly if they have seen advertisements or heard about it or be approached or referred by their primary care, secondary and adult care teams or community advocates.

Analysis

We will apply four strands of analysis to our data: (1) longitudinal individual-level case studies; (2) conversation analysis on recorded interactions; (3) statistical analysis of outcome and experience measures; (4a) health economic analysis of the cost of delivery; (4b) realist economic analysis of low frequency high-cost events and "near misses". These strands will be then synthesised in a joint display table;[21] analyses will apply an evidence appraisal tool, triangulation and stakeholder co-analysis. Our project Peer Research Group members will also be asked to attend co-analysis sessions and to co-design our dissemination plan and certain outputs.

1. Longitudinal individual-level case studies

Units of analysis

For Tier 1, Facilitation Tier of the programme theory: To refine understanding on how, when and for whom individual components of support trigger mechanisms and outcomes for DSWs (the facilitation tier of the programme theory) the evaluation will conduct individual cases studies for each DSW (n= minimum of 5). Please see Figure 4 for an example of a programme theory statement from the facilitation tier.

For Tier 2, Delivery Tier of the programme theory: To refine understanding of how the delivery of individual intervention components of the intervention, within different contexts, trigger mechanisms and (both proximal and distal) outcomes for people with dementia and carers (the delivery tier of the programme theory), individual case studies will be conducted. Persons with dementia and carer dyads recruited together will serve as the case study unit for analysis. If the person with dementia is recruited on their own, they will form the unit for analysis on their own (n= maximum of 90 case studies recruited, with the expectation numbers will decrease, due to attrition caused by death, participants moving out of the area and people with dementia moving into care homes permanently). Please see Figure 5 for an example of a programme theory statement from the delivery tier.

Coding framework

Our coding process utilises a realist logic, which ensures we can examine generative causation. The entire EPT (the delivery and facilitation tier of the programme theory – please see supplementary file 2 to review programme theory) will form the framework for coding of case study data, which will be managed in NVivo 12. The

EPT consists of a collection of realist statements (organised under core domains of

the programme theory e.g., engagement and disclosure, collaboration, peer

support) that have been constructed using an expanded variation of the traditional

'CMO' heuristic: Context (C) – (Intervention) Component (C) – Mechanism (M) -

Outcome (O). We used an expanded heuristic as existing realist evaluations have

shown that they can provide a deeper analysis into the individual components of a

complex intervention[22] - providing clarity on what casual explanation can be

attributed to specific intervention actions (or strategies/components/resources).[23]

Another reason for using this (expanded) CCMO within our evaluation was to aid

consistency in coding, analysis and dissemination by clearly defining what we mean

by the term 'mechanism' and 'outcome'.

To date, there have been varying (or missing) definitions of 'mechanism' used within

published realist evaluations.[23-25] Based on coding experiences in Phase 1, we

determined that it would be easier for researchers to code data to the EPT, if the 2

aspects of a (traditionally defined) mechanism' (resource – response) were split into

2 separate elements, as others[25] have also advocated (see Figure 5).

In addition, we wanted to distinguish between responses to intervention components

(resources) that involve i) a generative change in the targeted person's internal

reasoning (e.g., changes in beliefs/ thoughts, emotions, understanding), which can

alter their decision-making,[26] as a type of mechanism and ii) responsive changes in

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behaviour/actions. Some realist evaluations have viewed both types of responses as mechanisms, whereas others have only focused on one type of response (or chosen to define mechanisms differently),[27] we chose to only use the former type of response (reasoning) to define mechanisms, as the latter was for D-PACT purposes a (proximal) outcome of the intervention, and it enabled us more clearly examine how changes in reasoning led to changes in behaviour.

In addition to theorizing about proximal outcomes, we hypothesised what medium-longer term (distal) outcomes the intervention would result in. Please see Figure 5 for the definition of context, component, mechanism, and outcomes (proximal and distal) within our evaluation, along with an example of a CCMO statement from our current programme. Evidencing a realist theory of the distal and proximal outcomes will enable us to develop a comprehensive evidence-base and framework that will help define more fully the outcomes for the different actors, in different settings and across organisational levels and sectors i.e., our shift in focus from outcomes to value and impact (aim 2). By evidencing proximal as well as distal outcomes we will provide further insight into how those long term and far-reaching changes occur.

Coding process

Data pertaining to delivery and/ or mechanism/ outcome attainment will be coded to the relevant part of each CCMO statement. The framework and coding process has been designed to enable both deductive coding (capturing qualitative data that

provides insights related to each statement within our existing EPT) and inductive coding (capturing new insights, meaning, or refinements to existing theory) – see Figure 6 for an overview of the coding process that will be used.

Researchers are receiving ongoing training about how to code, applying a codebook (see supplementary file 3 for the delivery tier version of the codebook). Researchers will meet on a regular basis to review, discuss and compare their coding – resolving any inconsistencies in how they are coding and/or misunderstandings about the process.

Within case analyses

Once all the data have been coded for an individual case study, a within case analysis will be undertaken. This will be done within two matrix templates (one to organise each person with dementia and carer's coded data to the CCMO statements for the delivery tier of the EPT, and one to organise practitioner's coded data to the CCMO statements within the facilitation EPT) developed within Excel or word. When a carer and person with dementia are recruited together their data will be entered into a combined, dyadic matrix, which has a split carer/person with dementia column for each CCMO so that differences/similarities between CCMO occurrences for both member of the dyad can be observed.

The matrices will enable researchers to create a trajectory of change for each case

by exploring, through vertical columns, how individual CCMO occurrences may have

reoccurred/changed over time and whether individual CCMOs may have been more

likely to occur at certain time points i.e., early, or later in the intervention. It will also

allow the researcher to pull together data sources from similar time points to get a

better understanding of the interaction within and between individual CCMOs (e.g.,

ripple effects).[28] Some data sources may provide more insight in one aspect of the

CCMO configuration and the combining of evidence from different data sources will

reinforce/challenge the evidence the data sources provide individually.

Researchers will review DSW timesheets, intervention tools and participant medical

records for the time periods where a CCMO was evidenced to determine whether

evidence from these data sources could be used to corroborate/challenge the

existing qualitative evidence within the matrix. When data from these additional

sources appear to link to CCMOs within the matrix that data will be added to the

matrix. A small proportion of CCMO statements in the facilitation tier relate to other

actors and recipients e.g., GP surgeries and DSW supervisors. Data coded to these

statements will be amalgamated and analysed separately to explore context-

dependent mechanism activation, and any potential patterns in barriers/ facilitators,

in order to produce qualitatively generalisable insights.

Responses to items on the participants' outcome and experience measures, collected at 3 different time points (baseline, T1 (4-6 months of intervention support), T2 (9-12 months of intervention support), will be added to each participant's (people with dementia and carers) delivery matrix. This will allow us to further triangulate the data and consider links between evidenced occurrences of CCMOs up to the time of measurement data being collected (at each of the 3 time points) and the findings from the measurement scales. Summaries of what CCMOs were evidenced or not within the case matrices will be created for later use - see finalisation of the programme theory.

Cross case analyses

Researchers will review whether to conduct a cross case analyses by either using a matrix method -utilising the existing 'within case' matrices created through the within case analyses detailed above - or through the creation of one master NVivo file. The master NVivo file would contain each participants' coded data and would enable the use of matrix coding queries and node matrices to examine how coding for individual CCMO statements were distributed across the entire data set and for certain groupings of case studies e.g., case studies from the same site, case studies from the same type of participant (carer/person with dementia/DSW), with the same ethnicity/age group/socioeconomic background/professional background (for DSW) etc. In addition, we will be able to form participant groups for cross-case analysis by: 1) using interpreted 'themes' occurring throughout individuals' overall case context

memos (see coding process section for more detail) and 2) by using total and individual question scores from completed measures (e.g. participants who all scored low/high on feeling like a burden, or participants who scored highly on experience of care). 'Pilot' cross case analyses, the number of people recruited onto the study and the amount of time left for cross case analyses will inform the decision on which method to use.

Through this process the researchers will identify:

a) who experienced certain mechanisms and outcomes, triggered by intervention components, within a particular context

b) in what contexts the intervention components were not delivered or did not trigger intended mechanisms or lead to beneficial outcomes

c) whether people who reported medium-longer-term changes (positive or negative to their wellbeing, experiences of care, independence and engagement) experienced certain CCMOs more often than others and whether there were similar contextual factors shared by these sub-groups (e.g. their ethnic background, type of dementia, age, type of community).

Researchers will then return to the within-case matrices and summaries, using retroductive analyses[29] to explore possible reasons for differences found between different contexts. The aim is to understand general patterns across cases on how outcomes can be obtained for people from different contextual backgrounds. If there

are variations in recruitment progress across sites, resulting in varied amounts of data collected and coded at the time of cross site analysis, only partial cross-case analyses for some aspects of the programme theory may feasible.

2. Conversation analysis (CA) of video recordings of D-PACT intervention sessions from a sub-sample of case studies

CA can investigate how professionals and patients/clients communicate during certain activities.[30] While it does not attend to informants' internal cognitive or emotional states, it does micro-analyse, using recordings of real-time interactions, what people say and how they say it, and how this enables social actions to be achieved through communication (e.g., how a request is made). CA focuses on how participants negotiate shared understanding, and how all members of an interaction (e.g., patient/client and professional) shape the trajectory of the interaction, on a turn (of speakership) by turn basis. As such, CA, offers an opportunity to examine how specific interactional (intervention) components of interest are enacted in intervention sessions, e.g., how co-setting an agenda at the start of a support meeting may impact on patient participation e.g., a person with dementia topicalising issues for discussion.

Within the evaluation, CA is being applied to develop a more in-depth micro-level programme theory, specific to the interactional components and intended proximal outcomes (interaction behaviours of the intervention recipients) of the intervention to enable a better 'practice-level' understanding of how the intervention works. Video

recordings of support sessions from a sub-set of people with dementia and carer

case studies will be used to refine interactional aspects of the delivery EPT and a

collection of supervision recordings will be used to refine the interactional aspects of

the facilitation EPT.

By analysing other data sources (e.g., realist interviews, diary data and brief

interviews straight after a recorded support meeting) the researcher may additionally

be able to link communication practices to what internal responses participants

experienced - this possibility will be explored during the evaluation.

3. An assessment of quantitative outcomes/experiences measures over time

Quantitative data are being collected at 3 time points: T0 (pre-intervention), T1 (at 4-

6 months) and T2 (at 9-12 months), to explore changes over time for people with

dementia and their carers using outcome and experience measures (see Table 1)

which were tested in terms of their suitability and feasibility in Phase 1.

Baseline characteristics will be summarised using mean (SD) or median (IQR) for

continuous variables, and n (%) for binary or categorical variables. For the outcome

measures, summary statistics will be presented using mean (SD) or medians (IQR)

at each time-point, and for the change in scores from baseline, with corresponding

95% confidence intervals. Graphs tracking the trajectory of participants will be used

to visualise changes in outcome and experience measures over time. If there are

sufficient data, from a large enough sample, exploratory models for repeated

measures data will be fitted and these will explore within-subject (time-point) and

between-subject effects (key baseline covariates) on the outcome.. If there are not

sufficient data for models, we will test whether outcome/experience measures differ

according to variables of interest using simpler correlations and tests of significant

differences.

4. Exploratory health economics analysis

There will be two parts to our health economics analysis. The first will employ a

traditional HE approach, while the second will be exploratory, using a realist

approach.

   a) Cost of delivery and associated resource utilisation:

The estimation of direct costs associated with delivering the D-PACT intervention for

the whole system and for a range of individuals will be carried out in two ways:

- At a whole team level: estimating costs through the employed time of DSW

  and supervisor (not including time on research tasks) based on their NHS

  agenda for change grades.

- At individual patient level: through analysing the DSW time sheets to

  apportion above costs to individuals and to specific D-PACT tasks.

Additionally wider costs of health and social care, and carer costs will be described

and estimated from both our resource use questionnaires administered to people

with dementia and carers and data from practice Electronic Health Records (EHRs).

b) Assessment of contribution of D-PACT to changing the trajectory of high-cost events or near misses

We will conduct a realist cognisant, mixed methods economic analysis to examine the relationship between our intervention delivery and relatively rare but high-cost health and social care utilisation events or 'near misses' - avoidance of a negative event or unwanted change in care resulting from a sudden escalation in the patient's needs or risk (acute admissions, safeguarding and nursing home care). The rationale for developing this realist economic (RE) analysis is that high- cost events are relatively rate and should be analysed in isolation as they can distort economic results; a detailed qualitative realist analysis of care might provide evidence as to whether D-PACT activity is directed to changing the trajectory of such events, or even that in single cases whether the care actually contributed.

We will identify admissions to hospital or nursing/care home (or near misses) from patients' (only people living with dementia participants) electronic medical records (held at GP surgeries), using a search and extraction protocol developed from feasibility work using a small sample (4 patient records from a GP surgery at each site), but which can be refined if necessary. These records, DSW case notes (made during the 12 months of delivering the intervention for each participant) and qualitative data (coded as part of the case study analyses), will then be examined to explore evidence for impact of the anticipatory care component of D-PACT (e.g. DSW developing anticipatory care plan (ACP) which was then used; DSW engaging GP in active acute care). This review of records will be supplemented with qualitative

follow-up interviews with practitioners and/or carer if required. This RE analysis will incorporate analytic strategies described in the longitudinal cases study analysis above.

Synthesis

A mixed methods approach will be used to examine the findings from each strand of evaluation analyses to expand the programme theory and evaluate the intervention's value and impact (Aim 2). Bringing together analytic streams, though the use of a bespoke co-developed joint display table[21] focused on causal effects that generate value and impact at micro, meso and macro levels will enhance stakeholders' ability to make judgements about the likely benefit of the intervention.

Findings from each analysis stream will be summarised in joint display tables, with categories based on both pre-determined aspects of value and impact (e.g., reach; existing, evidenced programme theory statements regarding proximal and distal outcomes; and inductively developed aspects of value and impact (developed through this analysis and stakeholder engagement). The tables will also be organised according to (1) facilitation and delivery categories, to identify processes affecting DSWs and study participants, (2) proximal and distal outcomes and (3) micro, meso and macro levels. Throughout this process, patterns within the joint display table including areas of agreement or discordance will be examined through triangulation of the data (underpinning each analysis strand's findings) through a convergent mixed-methods model.[31]

This additional layer of analysis will involve stakeholder and colleagues' input into the design of the joint display table and the definition of value and impact that we use (e.g., their relatability to the real world) and their interrogation of our process (e.g. have we followed a clear analytic process and could another explanation for how value and impact was achieved be given). findings. Colleagues will include members of the wider team who are less closely tied to the data but have an understanding of the programme theory; stakeholders will include professionals and our PPI group. The analysis will also involve and the use of a bespoke self-appraisal tool, informed by realist[32] mixed method approaches[33] to assessing the transparency, rigor and quality of both the evidence and the analytic process used.

DISCUSSION

The proposed evaluation will fill gaps in current evidence on how post-diagnostic support based in primary care for people with dementia and their carers works, who such support works for and in what circumstances. These data will support decisions around post-diagnostic support for people with dementia and their carers. Our programme theory not only examines the delivery of such support but also the facilitation of those who provide that support. This will have implications for workforce training and support.

Our study will also demonstrate how to apply a realist design to evaluations where a randomised controlled trial design (RCT) is less appropriate, in line with latest MRC

guidance on the evaluation of complex behavioural interventions and their impact.[13]

For example it is increasingly being questioned whether the RCT, or an RCT alone,

is the most appropriate method for evaluating complex healthcare interventions due

to their lack of sensitivity to varying contexts, the length and complexity of the causal

chains linking the intervention with outcomes,[34-35] problems with recruitment due to

unengaging trial procedures and concerns as to whether standard outcome

measures will be sensitive to the varied and unpredictable achievements generated

by person centred interventions.[19,36] Our longitudinal mixed methods (non-

randomised) realist evaluation design is sufficiently flexible to support adjustable

recruitment processes. Experiences and data from recruitment in Phase 1 showed

that flexibility was necessary for person-centred recruitment that went at the pace of

the person with dementia and could be adjusted to suit other needs. This design

provides the same flexibility when collecting responses to our outcome and

experience (questionnaire) measures, where even those who are in more advanced

stages of dementia can be supported to respond (thus preserving their voice as

much as possible). An RCT design would have necessitated adhering to rigid

processes for how people living with dementia could respond to binary questioning

or the use of a full proxy.   This design also more easily accommodates a person-

centred, highly flexible intervention like D-PACT, which is constructed to be

responsive and adaptable to individual needs, for example bringing them into care

during increased times of perceived need. In this way we mirror real-world delivery

of complex health and social care services, which facilitates an examination of the

wider system in which this care would sit. Participants benefit too from adaptable

research processes and within-evaluation practitioner feedback sessions (that

involve discussion of emerging findings). Such sessions will enable timely and

necessary changes to be made to intervention delivery, ensuring the intervention

responds to, and caters for, different and evolving situations and needs. Our novel

approach places greater importance of qualitative data and commits to integrating

high volume and longitudinal qualitative data *with* quantitative data during analyses

to generate a breadth of evidence about what impact and value the intervention can

potentially have (and *how)* at various levels of care. This contributes to the growing

openness to alternative approaches (including realist ones) to evaluating complex

interventions.[34,13] Our work also addresses the question of whether such

approaches to evaluation do enough to establish the value and impact of an

intervention.

We do acknowledge that the lack of a randomised control group reduces our ability

to definitively compare outcomes with and without support; however we feel the

advantages of using a realist evaluation design outweigh those of using a RCT for

this particular project.

Authors' contributions

HW, LW and TMO contributed equally, as first authors, to the protocol.

Wheat H: Developed concept and funding application, led drafting of the entire protocol, developed and wrote analytic plans for longitudinal case studies and conversation analysis strands, co-developed/wrote the value and impact plan, and co-led latter stages of Phase 1 of the project (EPT development).

Weston L: Developed concept and funding application, led drafting of the protocol, developed and wrote analytic plans for longitudinal case studies and realist health economics strands and wrote introductory sections to realist evaluations.

Oh TM: Developed concept and funding application, wrote the (non-realist) aspect of the Introduction, co-wrote the Methods and Discussion and co-developed the realist health economics analysis and value and impact plan. Reviewed and edited each draft.

Morgan-Trimmer SMT: Contributed to funding application, supported the development of the analytic plans, in particular the longitudinal case studies and mixed methods analysis of each strand of analyses. Edited each version of the protocol.

Ingram W: Led the ethics application to the REC committee and co-developed recruitment plans and processes.

Griffiths S: Led early phases of stage 1 of D-PACT (Including PPI work, IPT development) and co-led subsequent phases with HW. Engaged in initial concept discussions for Phase 2.

Sheaff R: Contributed to funding application, supported the development of the analytic plans and sense checked drafts of the protocol.

Clarkson P: Contributed to funding application, oversaw plans for evaluation in NW site and sense checked drafts of the protocol

Medina- Lara A: Contributed to funding application, co-wrote realist health economics section of the protocol and sense checked drafts of the protocol

Musicha C: Wrote the statistical section of the protocol.

Spicer SG: Supported the development of the realist health economics plan, supported development of the statistical plan and sense checked drafts of the protocol.

Ukoumunne OC: Contributed to funding application, sense checked drafts of the protocol -supported statistical analyses section

Allgar V: Contributed to funding application, sense checked drafts of the protocol – supported statistical analyses section

Creanor S: sense checked drafts of the protocol - supported statistical analyses section

Quinn C: sense checked drafts of the protocol – supported PPI strategy.

Gude A: Co-led PPI involvement and contributed to the design and testing of the coding process.

Clark M: Contributed to funding application, sense checked drafts of the protocol - provided feedback on practitioner/service side of intervention and evaluation.

McCabe R: Contributed to funding application, sense checked drafts of the protocol - supported conversation analysis plans.

Batool S: Co-wrote sample and recruitment sections of the protocol, sense checked complete drafts of the protocol and facilitated stakeholder work.

Smith L: sense checked drafts of the protocol – supported design of recruitment processes and co-led PPI involvement.

Richards D: sense checked drafts of the protocol – supported design on recruitment processes

Shafi H: supported design on recruitment processes and facilitated PPI and stakeholder engagement/input

Warwick B: supported design of recruitment processes and facilitated PPI engagement/input

Lasrado R: supported design of recruitment processes

Hussain B: facilitating stakeholder involvement/input

Jones H: supported data collection from people with dementia and carers.

Sherriff I B.E.M sense checked drafts of the protocol/provided advice and guidance on national dementia policies

Dalkin S: sense checked drafts of the protocol

Bate A: sense checked drafts of the protocol

Robinson L: Contributed to funding application and sense checked drafts of the protocol

Byng R: Developed concept and funding application, edited each version of the protocol, contributed to all analysis plans and co-led/wrote plans for value and impact analyses within the evaluation.

Declaration of conflicting interests

The Authors declare that there is no conflict of interest.

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