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Dementia-PersonAlised Care Team (D-PACT) intervention

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Statistical Analysis Plan



Dementia-PersonAlised Care Team (D-PACT) intervention

ISRCTN: 80204146

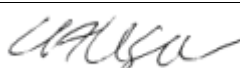
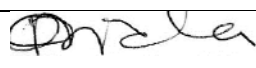
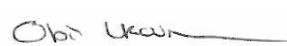
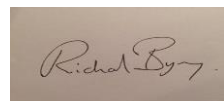

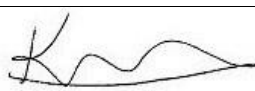
IRAS PROJECT ID: 264596

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ADMINISTRATIVE INFORMATION

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|---------------------------|--|
| Title of Trial | Realist informed mixed methods evaluation of the Dementia-Personalised Aligned Care Team intervention (D-PACT): a complex intervention for individuals with dementia and carers |
| Trial registration number | 80204146 |
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| SAP Version | Draft 1.0 (06 February 2024) |
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Abbreviations

| | |
|--------|--|
| AE | Adverse Event |
| CI | Chief Investigator |
| CMHT | Community and Mental Health Teams |
| D-PACT | Dementia Person Aligned Care Team |
| DSW | Dementia Support Worker |
| EID-Q | Engagement and Independence in Dementia Questionnaire |
| GP | General Practice |
| IQR | Interquartile range |
| IwD | Individual with dementia |
| ISRCTN | International Standard Randomised Controlled Trials Number |
| mCWS | Modified version of Carer Wellbeing and Support |
| MLM | Multilevel model |
| MoCA | Montreal Cognition Assessment |
| PCN | Primary care networks |
| PERCCI | Person-Centred Community Care Inventory |
| QOF | Quality and Outcomes Framework |
| SAE | Serious adverse events |
| SAP | Statistical Analysis Plan |
| SD | Standard deviation |
| SNOMED | Systematized Nomenclature of Medicine |

1 INTRODUCTION

1.1 BACKGROUND AND RATIONALE

Dementia is a progressive set of symptoms that includes loss of short-term memory and problem-solving ability, communication problems and loss of visuospatial skills. In most cases, dementia syndrome is the result of an underlying neurodegenerative condition such as Alzheimer's Disease. Currently, over 850,000 people in the UK live with dementia and if the prevalence of dementia remains the same, the number is predicted to increase to 1,142,678 by 2025¹. The overall economic impact of dementia in the UK is £26.3 billion per annum with two thirds of this cost being borne by people living with dementia and their families². With the risk of developing dementia increasing with age, rising from 1 in 14 individuals aged 65 to 1 in 6 individuals aged 85², and with 72% of individuals who have dementia also living with another medical condition or disability, our growing elderly population will have a significant impact on NHS services. There are a range of issues faced by an individual with dementia (IwD) and their carer's and families including physical healthcare, mental wellbeing and health-related quality of life and currently there are a number of dementia support worker (DSW) type roles which aim to achieve a variety of services from signposting, emotional support through to admission prevention. The distinction between the various types of DSW roles is often unclear and while some provide active liaison between primary, secondary, and social care, this function is not universal. While these roles are valued¹⁻³ there is lack of evidence as to what the best aspects of their support are, where it would be best delivered and what the costs/benefits of delivering such a service might be.⁴⁻⁶ The Dementia Person Aligned Care Team (D-PACT) Dementia Support project proposes integrating a DSW into the primary care setting, incorporating services identified as important to improve the health, wellbeing and quality of life of IwD and their carers. The project aims to develop and establish whether it is effective and cost-effective to include an additional supervised DSW into the primary care team for improving physical healthcare, mental wellbeing and health-related quality of life, compared to treatment as usual for a IwD and their carers/families following diagnosis.

The feasibility study involved working with stakeholders to identify and test outcome measures that are meaningful to IwDs and their carers. We also conducted a mapping exercise where we reviewed whether the measures we used were asking questions relevant to our programme theory i.e. exploring intended outcomes and experiences of the intervention. Through this work, two measures were identified as fit for purpose for use in D-PACT2. This study will build on the feasibility phase with an aim of achieving an enhanced understanding of the D-PACT intervention delivery; to further refine the programme theory; to gather evidence about the potential value and impact of the D-PACT intervention and to further test our developed methods for conducting community-based dementia studies. This will be done via a realist-informed mixed-methods longitudinal approach. Additionally, D-PACT2 will extend our previous work by engaging various under-served communities and recruiting participants from these important groups on which more research is needed.

The study protocol includes a brief outline of the statistical methods to be employed in the analysis of the evaluation of the D-PACT intervention data. The purpose of the Statistical Analysis Plan (SAP) is to provide full details of the planned statistical methods to be used in the primary report of the results. The SAP has been drafted following the STROBE guidelines for observational studies.⁷

1.2 STUDY AIMS AND OBJECTIVES

The study has three broad aims and related objectives:

- 1) To understand how the D-PACT intervention is – and should be – delivered in varied settings (including to different communities) and further refine the programme theory. This will be achieved through building on initial feasibility work and testing D-PACT in more varied organisational settings, including with patient groups often missing out on care, and involving the wider and rapidly developing primary care team, such as social prescribers.
- 2) To explore the potential value and impact of the D-PACT intervention. A range of data sources will be used to address this aim, including high volume qualitative data collected longitudinally, combined with an exploratory analysis of quantitative measures (outcome and experience measures) collected at three time points. This will also include quantifying change over time for key measures of cost and impact. Baseline-to-follow up comparisons will be used to explore intervention effects, keeping in mind the limitations of a before-and-after comparisons.
- 3) To contribute to methodological development of community-based dementia studies, building on our work on face-to-face and remote recruitment and measuring outcomes for a group with variable capacity. This will focus on the proportion recruited and time taken to recruit the participants.
- 4) A psychometric analysis to be led by external collaborators will also be conducted and a separate SAP will be developed for this.

The planned analysis in this SAP will focus on Objectives 2, and the second part of Objective 3 (describing the proportion recruited and time taken to recruit participants), while the psychometric analysis will be done by the external collaborators.

2 METHODS

2.1 STUDY DESIGN

D-PACT2 will take place over two years (October 2021-2023) and will be implemented via two inter-related study components (Realist Evaluation and Methodological Development) which will address the three study aims. A mixed methods longitudinal study will be conducted in individuals with dementia, recruited with or without their carers, as well as dementia support workers (DSWs), their supervisors, general practices (GPs) and practice staff. High volume longitudinal qualitative (interviews, recordings, reflections, diaries, notes, observations, electronic health records) and quantitative data (outcome and experience measures, resource use questions, timesheets) will be collected as appropriate from IwD/carers participants and/or practitioner

participants. This multi-purpose data set will be analysed using a range of analytic methods to address our listed aims, some of which are the focus of this SAP.

2.2 STUDY SETTING

The study will take place across two geographical regions, the Southwest (SW) and the Northwest (NW) of England. Primary care networks (PCNs) in three sites will be approached. The three sites will represent rural communities (Devon), coastal/poor communities (Plymouth/Torbay, Devon) and urban/ethnic minorities (Greater Manchester) respectively. Individual GP practices (except those with very small Quality and Outcomes Framework (QOF) dementia registers) will be approached once the PCN has endorsed the study. The number of GP practices in each site will depend on the size of the individual participating practices.

2.3 INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

- People with a clinical diagnosis of dementia identified through pre-defined Systematized Nomenclature of Medicine (SNOMED) codes, and their carers.

Exclusion criteria:

- Those who are resident outside the local authority boundary to be served.
- 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).
- Those within care home setting.
- Those receiving substantial support from Community and Mental Health Teams or CMHT (defined as input within the last four months and not due to be discharged within the next two months).
- Those who present as high risk and, after referral, are taken on by CMHT.
- Those with open safeguarding referrals and ongoing planned CMHT care.
- Those with a longstanding history of mental health difficulties and currently receiving care from other mental health teams.
- Diagnosed with an end stage physical health problem (e.g. cancer, severe heart failure) with substantive multi-disciplinary palliative

2.4 RECRUITMENT

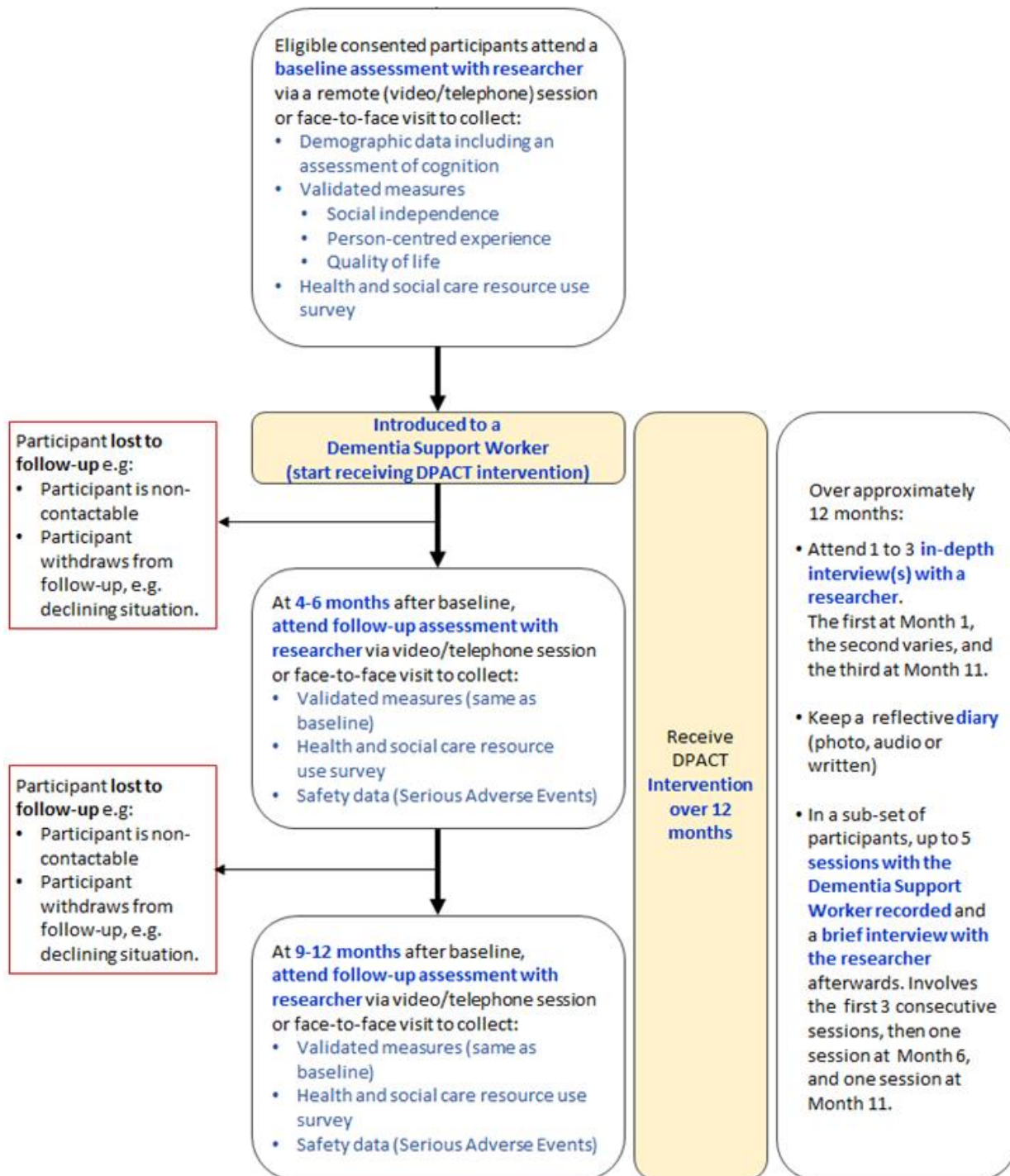
The study will aim to recruit participants in the two regions (SW and NW), with an estimated target of up to 90 participants with dementia and carers in each of the regions (up to 180 participants in total).

Baseline data will then be collected from eligible participants who consent (Figure 1). They will then be introduced to a DSW to start receiving the D-PACT intervention.

2.5 DATA TO BE COLLECTED

The study will collect quantitative data at baseline and at the follow-up visits at 4-6 months and 9-12 months (See Figure 2 in the Appendix). The assessments will be done remotely (telephone/video) or via face-to-face visits.

Figure 1: Patient flow chart



2.5.1 Baseline Data

Baseline data will be collected via a remote telephone/video call or through a face-to-face meeting with a researcher. At baseline, the Montreal Cognition Assessment (MoCA)8 will be completed

with the IwD. In addition, the following demographic data will be collected from the IwD (or by the carer as a proxy for the IwD where IwD is unable to self-report) and the carer participants:

- Sex
- Ethnic group
- Preferred language
- Relationship status (of IwD to carer)
- Who individual with dementia lives with
- Carer employment status
- Current employment (if any)
- If no longer working, last/best job
- Current income (IwD and carer)
- If no longer working, last income received
- Highest education achieved (includes post-school qualifications, including those from apprenticeships and other training at work)
- Housing tenure (owners occupied, local authority and housing association tenants, privately rented accommodation)
- A deprivation indicator

2.5.2 Person with Dementia, Carer and Clinician-Reported Measures

The following outcome/experience measures will be collected at baseline, 4-6 months, and 9-12 months after baseline:

- **Engagement and Independence in Dementia Questionnaire (EID-Q)**⁹ administered to the IwD (or by the carer as a proxy for the IwD where IwD is unable to self-report). Supplementary questions in collaboration with the developers of these measures will also be asked as part of the score.
- Experience of care determined through the **Person-Centred Community Care Inventory (PERCCI)**¹⁰ questionnaire administered to the IwD (or by the carer as a proxy for the IwD where IwD is unable to self-report). Supplementary questions, created in collaboration with the developer, administered to the IwD (or by the carer as a proxy for the IwD where IwD is unable to self-report) alongside the PERCCI. The supplementary questions will be analysed separately as part of the psychometric analysis.
- Modified version of Carer Wellbeing and Support (mCWS)^{11,12} administered to the carer.

3 STATISTICAL ANALYSES

3.1 STUDY POPULATION

The data of the flow of participants from consent to completion of the study will be presented in a flow diagram, indicating the number who attended each visit and completed all outcome questionnaires at each visit as shown in Figure 1 in the Appendix. This will include details on

participants who discontinue, withdraw, or are lost to follow-up at any point during the study period.

3.2 PARTICIPANTS' DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Baseline characteristics will be summarised using means and standard deviations (SD) or medians and interquartile ranges (IQRs) for continuous variables, and numbers (n) and percentages (%) for categorical variables as shown in Table 1 in the Appendix.

3.3 PATIENT, CARER AND CLINICIAN-REPORTED OUTCOME MEASURES

The EID-Q, PERCCI and mCWS scores will be derived from their respective questionnaires as detailed below:

- 1) **The EID-Q⁹ is the** sum of items 1 to 26 of the EID-Q questionnaire, each scored from 0 to 4, where 0 is “not true at all”, 1 is “rarely true”, 2 is “sometimes true”, 3 is “often true” and 4 is “true nearly all the time”. A higher score (possible range 0 to 104) is indicative of a better outcome.
- 2) **The PERCCI¹⁰ is the** sum of 12 items, each scored from 0 to 3 where 0 is “never or rarely”, 1 is “sometimes”, 2 is “often” and 3 is “always”. A higher score (possible range 0 to 36) means better quality of care experience for the IwD. On top of calculating the overall score from the individual items, the Item Response Theory (IRT) Partial Credit Model (PCM) will be fitted to the PERCCI data at each time point.^{11,12} Empirical Bayes estimates will be used to predict the latent scores this model. Plots of the calculated scores versus the latent variables should follow the usual logit shape. Predicted latent scores will only be obtained for participants with at least one response in the PERCCI questionnaire. The PCM model might also be adjusted for participant characteristics if appropriate. The PCM model works well in the presence of missing items as it handles missing data through probabilistic modelling. It utilizes the available information and estimates parameters based on the observed responses, leverages the hierarchical structure of the response categories.
- 3) **The mCWS^{13,14} which is** the sum of all 32 items in Section A (well-being) and 17 items in Section B (support). Each item in Section A is scored between 0 = “a lot” and 4 = “not at all” and in Section B each item is scored between 0 = “very dissatisfied” and 3 = “very satisfied”. A higher CWS total score (possible range 0 to 147) indicates better carer wellbeing and a higher level of support. The CWS was modified to remove the text “..a mental health problem” from the questionnaire title and introduction section, and the phrase “You don’t have to be a person’s main carer or live at the same address as them” from the introduction. mCWS scores will be higher for respondents who report better well-being and higher satisfaction with support.

A summary of the available data for each outcome, by region, as presented in Table 2 in the Appendix will be used to assess the completeness of the collected data.

Summary statistics of the collected quantitative outcome and experience measures at each time point (baseline, 4 to 6 months and 9 to 12 months) will be presented using means (SDs) or medians (IQRs) as in Table 3 in the Appendix.

The correlation between baseline and follow-up scores will be reported, with corresponding confidence intervals (CIs), for each of the outcome measures (Table 4 in Appendix).

Bivariate correlations between the outcomes themselves (EID-Q, PERCCI and mCWS) at each time point will also be reported with their CIs, Table 5 in Appendix.

The changes in scores from baseline to the first follow-up (4 to 6 months) and from baseline to the second follow-up (9 to 12 months) will be reported using means (SDs) or median (IQR) (Table 6 in Appendix). Because of the nature of this small observational study, we will present 95% CIs, but will not report p-values. Bar charts and boxplots, where appropriate, will be used to explore if there are any changes in outcomes over the course of follow-up. The plots will be stratified by region (northwest vs southwest) to compare scores across the 3 time points (baseline, 4 to 6 months and 9 to 12 months).

3.4 MIXED-METHODS SUB-STUDY

An analysis will be undertaken drawing on the themes of interest identified in the qualitative analysis, if quantified in the quantitative data. The convergent design where quantitative and qualitative data are collected simultaneously and analysed separately will be used. From the resulting analysis, we will combine or compare the results from the two methods to come up with an overall conclusion. The aim is to explore potential relationships between the themes and the outcome measures (EID-Q, PERCCI and mCWS). Descriptive statistics will be used to summarise the data.

3.5 MISSING DATA

For the outcomes, missing data from individual questions will be imputed using recommended methods. Mean imputation will be used at the 10% level for the EID-Q, where all participants with 3 or less items missing had their missing values replaced with the mean of the remaining items.⁹, Mean imputation will also be done for respondents who answered at least 50% of items on either scale of the mCWS (wellbeing and support). Data will be imputed data for every missing item on that scale using a person-specific mean calculated on the basis of the mean score of non-missing values for that respondent.^{15, 16} We will not impute missing data for the PERCCI as the Rasch model robustly handles situations where some of the data is missing.

3.6 STATISTICAL SOFTWARE

The statistical analyses will be undertaken using StataSE version 17 or later, supplemented where required by R.

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Appendix: Examples of tables and figures

Figure 1: Example flow chart showing visit attendance for IwD

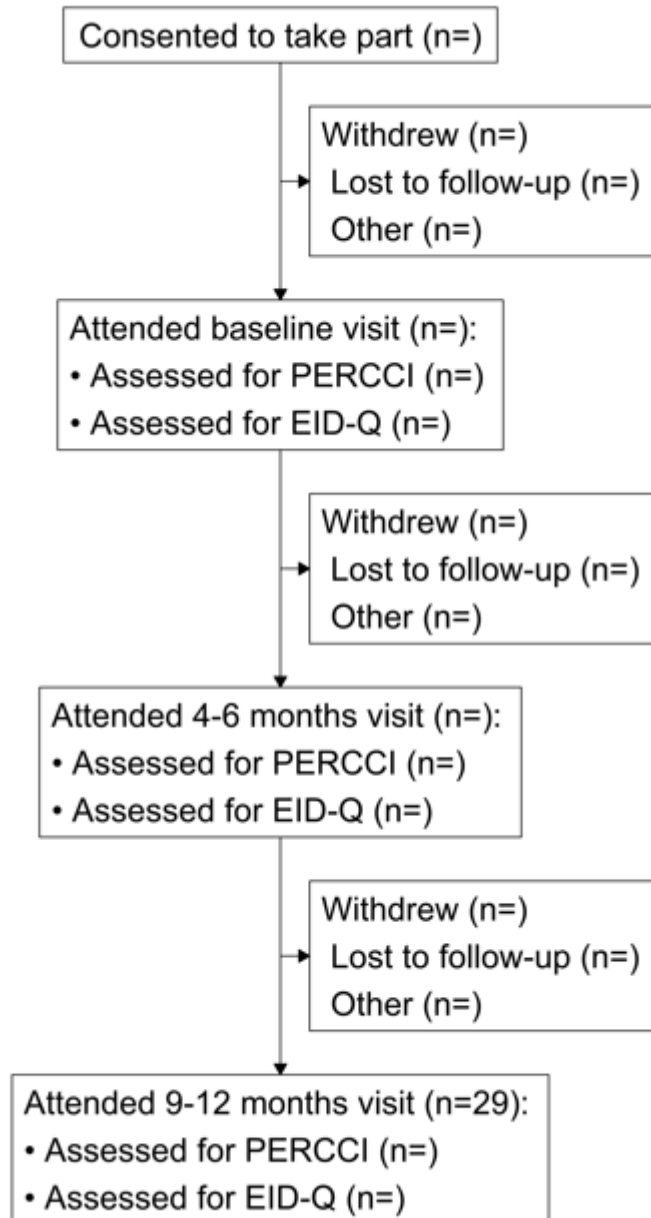


Table 1: Summary statistics of baseline and demographic participant characteristics by region

| | Southwest (N =) | Northwest (N =) | Overall (N =) |
|--|---------------------|---------------------|-------------------|
| Sex n (%) | | | |
| Male | | | |
| Female | | | |
| Ethnicity n (%) | | | |
| White | | | |
| Asian | | | |
| Black | | | |
| Mixed/Multiple | | | |
| Other | | | |
| Preferred language n (%) | | | |
| English | | | |
| Other (Gujurati) | | | |
| MoCA Score | | | |
| Mean (SD) [range] | | | |
| Median (IQR) | | | |
| Relationship status n (%) | | | |
| Single | | | |
| Married/Civil partnership | | | |
| Divorced/Separated | | | |
| Widowed | | | |
| Other | | | |
| Relationship (IwD to carer) n (%) | | | |
| Parent | | | |
| Spouse/partner | | | |
| Brother/sister | | | |
| Child | | | |
| Rather not say | | | |
| Other | | | |
| Living Arrangements n (%) * | | | |
| Alone | | | |
| Spouse/Partner | | | |
| Parent/s | | | |
| Sibling/s | | | |
| Child/ren | | | |
| Other | | | |
| Current employment, IwD n (%) | | | |
| Employed full time | | | |
| Employed part time | | | |

| | | | |
|--|--|--|--|
| Unemployed | | | |
| Retired | | | |
| Other | | | |
| Current employment, carer n (%) | | | |
| Employed full time | | | |
| Employed part time | | | |
| Unemployed | | | |
| Retired | | | |
| Other | | | |
| Last/best job, not working n (%) | | | |
| Current income (lwD) n (%) | | | |
| £0 | | | |
| £1 to £9,999 | | | |
| £10,000 to £24,999 | | | |
| £25,000 to £49,999 | | | |
| £50,000 to £74,999 | | | |
| Over £75,000 | | | |
| Current income (Carer) n (%) | | | |
| £0 | | | |
| £1 to £9,999 | | | |
| £10,000 to £24,999 | | | |
| £25,000 to £49,999 | | | |
| £50,000 to £74,999 | | | |
| Over £75,000 | | | |
| Previous income (lwD not working) n (%) | | | |
| £0 | | | |
| £1 to £9,999 | | | |
| £10,000 to £24,999 | | | |
| £25,000 to £49,999 | | | |
| £50,000 to £74,999 | | | |
| Over £75,000 | | | |
| Highest education n (%) | | | |
| Secondary school (16 years) n (%) | | | |
| A levels/Higher School | | | |
| College or undergraduate degree | | | |
| Postgraduate degree | | | |
| PhD (or equivalent) | | | |
| Other | | | |
| Housing tenure n (%) | | | |
| Owned | | | |
| Privately rented | | | |

| | | | |
|------------------------------|--|--|--|
| Rented (authority) | | | |
| Live with family | | | |
| Other | | | |
| IMD Deprivation Score | | | |
| Mean (SD) [range] | | | |
| Median (IQR) | | | |

*Participants can provide data in more than one category – percentages will not necessarily add to 100%

Table 2: Completeness of proposed primary and secondary outcomes by region

| Outcome | Time Point | Southwest Number recruited | | Northwest Number recruited | | Overall Number recruited | |
|---------|----------------|----------------------------|-------------------------|----------------------------|-------------------------|--------------------------|-------------------------|
| | | Attended Visit, n (%) | With Valid Score, n (%) | Attended Visit, n (%) | With Valid Score, n (%) | Attended Visit, n (%) | With Valid Score, n (%) |
| EID-Q | Baseline | | | | | | |
| | 4 to 6 months | | | | | | |
| | 9 to 12 months | | | | | | |
| PERCCI | Baseline | | | | | | |
| | 4 to 6 months | | | | | | |
| | 9 to 12 months | | | | | | |
| mCWS | Baseline | | | | | | |
| | 4 to 6 months | | | | | | |
| | 9 to 12 months | | | | | | |

Table 3: Summary statistics for the proposed primary and secondary outcome measures by region

| Outcome | Time Point | Southwest | | | | Northwest | | | | Overall | | | |
|---------|----------------|-----------|-----------|--------------|-------|-----------|-----------|--------------|-------|---------|-----------|--------------|-------|
| | | N | Mean (SD) | Median [IQR] | Range | N | Mean (SD) | Median [IQR] | Range | N | Mean (SD) | Median [IQR] | Range |
| EID-Q | Baseline | | | | | | | | | | | | |
| | 4 to 6 months | | | | | | | | | | | | |
| | 9 to 12 months | | | | | | | | | | | | |
| PERCCI | Baseline | | | | | | | | | | | | |
| | 4 to 6 months | | | | | | | | | | | | |
| | 9 to 12 months | | | | | | | | | | | | |
| mCWS | Baseline | | | | | | | | | | | | |
| | 4 to 6 months | | | | | | | | | | | | |
| | 9 to 12 months | | | | | | | | | | | | |

Table 4: Example table of correlation of IwD and carer outcome measurements by visit

| | Correlation between baseline and follow-up measures (two-sided 95% Confidence Intervals) | | |
|--------|---|----------------------------------|------------------------------------|
| | Baseline and 4-6 months (N=) | Baseline and 6-12 months (N=) | 4-6 months and 6-12 months (N=) |
| EID-Q | | | |
| PERCCI | | | |
| mCWS | | | |

Table 5 : Example table of correlation summary statistics for the IwD and carer outcome measurements

| | Correlation between outcomes at each visit (two-sided 95% Confidence Intervals) | | |
|-------------|--|-------------|-----------|
| | EID-Q (N=) | PERCCI (N=) | mCWS (N=) |
| Baseline | | | |
| EID-Q (N=) | | | |
| PERCCI (N=) | | | |
| mCWS (N=) | | | |
| 4-6 months | | | |
| EID-Q (N=) | | | |
| PERCCI (N=) | | | |
| mCWS (N=) | | | |
| 6-12 months | | | |
| EID-Q (N=) | | | |
| PERCCI (N=) | | | |
| mCWS (N=) | | | |

Table 6: Example table of change in IwD and carer outcome measurements over time

| Change from baseline to first follow-up (4-6 months) | | | | | | | | |
|---|----------|-----------|--------------|-------------|-----------|--------------|------------------|--------|
| | Baseline | | | 4-6 months | | | Mean differences | |
| | N | Mean (SD) | Median [IQR] | N | Mean (SD) | Median [IQR] | Crude | 95% CI |
| EID-Q | | | | | | | | |
| PERCCI | | | | | | | | |
| mCWS | | | | | | | | |
| Change from baseline to end of follow-up (9-12 months) | | | | | | | | |
| | Baseline | | | 9-12 months | | | Mean difference | |
| | N | Mean (SD) | Median [IQR] | N | Mean (SD) | Median [IQR] | Crude | 95% CI |
| EID-Q | | | | | | | | |
| PERCCI | | | | | | | | |
| mCWS | | | | | | | | |