PriDem Study (Workstream 4)
Statistical Analysis Plan

Version 1.0

16 January 2023

1 Administrative information

1.1 Study full title

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

1.2 Purpose

This Statistical Analysis Plan (SAP) describes a protocol-specified analysis of the PriDem Study (Workstream 4). The SAP contains details of quantitative analyses only and does not describe any qualitative and/or economic analyses.

1.3 Protocol version

This SAP has been written based on information contained in the study protocol version 6.0, dated 8 August 2022. Full details of the study design, population, intervention, comparison and outcome variables may be found in the protocol.

1.4 Study registration

This study was prospectively registered with ISRTCN (11677384) and IRAS (294881). Confidentiality Advisory group support has been obtained (ref.: 21/CAG/0182)

1.5 Authorship

This SAP has been written by Dr. Chen Qu (Study Statistician) and Dr. Aidan O'Keeffe (Lead Statistician).

1.6 SAP revisions

Version History Log

Version	Date	Changes
1.0	16/01/2023	N/A (Version 1.0)

1.7 Signatures

The undersigned confirm that the SAP has been agreed and accepted and that the Study Statistician agrees to conduct the analyses in compliance with the approved SAP. Major deviations from the SAP will be agreed in advance before implementation. All deviations from the SAP will be explained, documented and reported accordingly.

Lead Statistician:

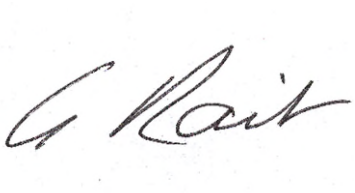
Signature: 

Date: 16/01/2023

Print Name (in full): Aidan O'Keeffe

Position: Associate Professor in Statistics, University of Nottingham; Honorary Associate Professor, UCL

Principal Investigator:

Signature: 

Date: 24/01/23

Print Name (in full): Greta Rait

Position: Prof Primary Care and Health Services Research, UCL

2 List of Abbreviations

AE	Adverse Event
AR	Adverse Reaction
CAG	Confidentiality Advisory Group
CI	Chief Investigator
C-DEMQOL	Carer specific dementia quality of life measure
CRF	Case Report Form
CSRI	Client Service Receipt Inventory-shortened, adapted for PriDem
DEMQOL	Dementia quality of life measure
DEMQOL-proxy	Dementia quality of life measure proxy
EQ-5D-5L	Quality of life measure
HADS	Hospital Anxiety and Depression Scale
ISRCTN	International Standard Randomised Controlled Studies Number
MoCA	Montreal Cognitive Assessment
NPI	Neuropsychiatric inventory
PCN	Primary Care Network
PLWD	Person Living with Dementia
QALY	Incremental cost per quality adjusted life year
QOF	Quality Outcomes Framework
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction

3 Introduction

3.1 Background

The overall aim of the PriDem programme is to develop and evaluate an acceptable, feasible and sustainable model of evidence based, person-centred, primary care led post diagnostic dementia care to maintain and improve quality of life for people with dementia and their families. The PriDem intervention comprises multiple components which are focused on three interlinked areas of systems of support, tailored care and capacity building.

3.2 Principal research objectives

The primary feasibility objectives are to assess:

- The rates of recruitment and retention at follow-up.
- The acceptability and engagement with both the intervention and implementation study procedures
- The proportion of people with dementia whose notes are reviewed for service use data at participating practices.
- The number of patient records reviewed in the care plan audit (overall and by recruited practice).

The primary implementation objectives are to assess:

- If the PriDem intervention increases the number of people with dementia with a personalised care plan.
- If the PriDem intervention can be implemented in wider primary care settings.

3.3 Secondary research objectives

Secondary feasibility objectives are to assess:

- The feasibility and acceptability of engaging and training clinical dementia specialists and embedding within existing care pathways and models of service delivery.
- Whether the intervention can be delivered as intended.
- What are the resource requirements to access, collect and analyse the data.

- The acceptability and appropriateness of the potential primary and secondary implementation outcomes.

Secondary implementation objectives are:

- To examine how the intervention is delivered and adapted within practice.
- To identify context and delivery variations/factors which influence embedding the intervention components in usual care.
- To identify factors that increase adoption, coverage and sustainability of the intervention including acceptability, appropriateness, fidelity.
- To collect data on the resources needed for implementation.
- Determine the cost-effectiveness of the PriDem Intervention and its implementation.
- Explore the context, mechanisms and impact of the intervention for PLWD, CPs and professionals and the barriers and levers to implementation at scale using mixed methods, such as efficiency, safety, effectiveness, equity, patient-centredness, satisfaction and timeliness.

4 Study Methods

4.1 Study design

The study is non-randomised, will run for 15 months in total and will be conducted in four Primary Care Networks (PCNs), two in the Northeast of England and two in the South East of England.

Participating sites and participants will have exposure to the intervention over a twelve-month period. Routine and study-specific data will be collected pre-intervention (baseline), at four months and 9 months (see Protocol Version 6.0 for further details).

4.2 Sample size

The nature of the study (a feasibility and implementation study) implies that a power-based formal sample size calculation related to a hypothesis test of interest would not be appropriate. With regard to numbers of practices and participants: four PCNs will be recruited to participate in the study. It is anticipated that each recruited PCN will contain up to 5 practices. Within each PCN site, we aim to recruit approximately

20 people living with dementia. We expect to recruit approximately 80 participants into the study within the first four months.

It is anticipated that pre-intervention, approximately 40% of people diagnosed with dementia have a personalised care plan. Following the intervention phase, we would like this to increase to at least 50% of people diagnosed with dementia. As such, a sample size of 215 people with dementia is sufficient to detect an increase in the proportion of people with a personalised care plan of at least 0.1, using a one-sided Z-test at the 5% significance level with 90% power. This assumes that the current proportion of people who have a personalised care plan is 0.4.

4.3 Interim analysis

This study is low risk and therefore an interim analysis will not be undertaken. We will report on feasibility in terms of recruitment rates and completeness of data collection (as well as the acceptability and adaptation for the intervention).

5 Statistical Principles

5.1 Confidence intervals and p-values

The 5% level will be used to determine statistical significance and confidence intervals will be reported at the 95% level.

5.2 Analysis Populations

All analyses shall be performed on an intention-to-treat basis. Any participants that have withdrawn from the study, and who withdraw permission to keep and use their data, will be excluded.

6 Study Population

6.1 Recruitment and retention

A CONSORT diagram will be presented to provide a detailed description of participant numbers at each time point during the study. In addition, a table summarising the number of participants who have been withdrawn at each stage of the study and reasons for withdrawal (if supplied) will be presented.

6.2 Baseline characteristics

Demographic information collected at baseline will be presented in a table. Numerical variables will be summarised using either means and standard deviations or medians and interquartile ranges. Categorical variables will be summarised using counts and proportions. The number of missing observations will be reported.

For participants recruited to the PriDem study, the following baseline characteristics of people living with dementia and/or their carer will be summarised:

a) Age (in years)

b) Gender

c) Ethnicity (defined as: [White], [Black, African, Caribbean or Black British], [Asian or Asian British], [Mixed or Multiple Ethnic Groups], [Not specified/Do not wish to specify])

d) Site (North East or South East)

e) Relationship of PLWD to carer (defined categories: Spouse, Partner, Son/Daughter, Son/Daughter in law, Brother/Sister, Other relative, Friend, Neighbour, Other)

f) Dementia diagnosis (defined categories: Alzheimer's disease, Vascular, Lewy Body, Mixed, Other or Unknown)

g) Time since dementia diagnosis

h) Social deprivation score (using the postcode-based Index of Multiple Deprivation (IMD) quintile)

For those whose patient records are audited as part of the study, variables a)-d) and f)-h) will be reported.

7 Analysis

7.1 Outcomes

7.1.1 Primary outcome

Primary feasibility outcomes are:

- Number of PCNs and practices that are recruited to participate in the study.
- Proportion of target number of audits completed, overall and within each practice based on its stratified sampling target.

- Proportion of participants with dementia for whom service use data is extracted from medical records at participating practices.

The primary implementation outcome is a binary measure that records whether or not a recruited person with dementia has a personalised care plan in place by the end of the study. For each participant where an audit of notes is conducted, the binary variables:

1. "Does the person living with dementia have a care plan?" (YES/NO)

2. "Did the person with dementia and/or their carer attend the meeting" (here a 'meeting' refers to the occasion when a care plan was determined) (YES/NO)

will be used to determine the primary implementation outcome. A person living with dementia with care plan will be classed as having a personalised care plan in place if answers to both 1. and 2. are 'YES'.

7.1.2 Secondary outcomes

People living with dementia:

- DEMQOL (Dementia Quality of Life measure)
- EQ5D-5L (quality of life)

Carers of the person living with dementia

- DEMQOL-Proxy (Dementia Quality of Life measure)
- EQ5D-5L Proxy (quality of life)
- NPI (Neuro-Psychiatric Inventory score)

Carers about their health and wellbeing

- HADS (Anxiety and Depressions scale)
- C-DEMQOL
- EQ5D-5L

Service use data from the CSRI (Client Service Receipt Inventory – Adapted for PriDem):

- Number of each of the following service uses/outpatient appointments during follow-up:
    - Geriatrician
    - Hospital memory clinic
    - Speech and language therapist
    - Neurologist
    - Psychiatrist
    - Physiotherapist
    - Occupational therapist

  - Psychologist
  - Other hospital outpatient appointment

- Number of each of the following emergency service uses during follow-up:
  - NHS Direct or 111 Call
  - Emergency (999) Call
  - Paramedic attendance only
  - Paramedic attendance AND transport to hospital by ambulance
  - Accident and Emergency attendance without ambulance transport

- Number of instances of the following overnight/inpatient stays during follow-up:
  - Unplanned (emergency) hospital stay
  - General medical planned (elective) hospital stay
  - Psychiatric inpatient hospital stay
  - Specialised rehabilitation service overnight stay
  - Local or district rehabilitation overnight stay

7.2 Primary outcome Analysis

For feasibility, continuous outcomes will be summarised using summary statistics at each time point (for example mean, median, standard deviation, maximum and minimum). Categorical variables will be summarised at each time point using counts and percentages.

For implementation, the primary outcome will be summarised as the proportion of people who have a personalised care plan with an associated 95% confidence interval. In addition, a one-sided, one-sample Z-test at the 5% significance level will be used to test the null hypothesis that the proportion of people with a personalised care plan $= 0.4$ against a one-sided alternative that this proportion is > 0.4.

7.2.1 Model checking

Assumptions made when conducting hypothesis tests or fitting models will be checked.

7.3 Secondary outcome analyses

The secondary outcomes will be assessed using analogous methods to those used for the primary outcome. All analyses of secondary and other outcomes should be considered as supportive analyses.

7.4 Sensitivity analyses

There are no planned sensitivity analyses.

7.5 Subgroup analyses

There are no planned subgroup analyses.

7.6 Missing data

All analyses will be complete case, with no adjustment made for missing data. Numbers of missing observations will be summarised at each time point for each variable.

7.7 Adverse event reporting

The number, causality, expectedness and severity of adverse events (if any) will be reported at each time point. The number of participants who experience adverse events will likewise be reported.

8 Summary of Changes

This Statistical Analysis Plan does not propose any changes to the statistical approach described in the protocol.

Any changes to the Statistical Analysis Plan made after this document has been signed off will be recorded. In addition, significant changes will be fully justified and approved before implementation.